Exhibit A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

United States of America, *et al.*, v. Gilead Sciences, Inc.	))))	Case Number: Civil No. 17-cv-3523

Expert Report of Virginia B. Evans

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I. INTRODUCTION

I have been engaged by the law firm, Miller Shah LLP ("Counsel for Plaintiff Relators"), to perform a review of and offer an objective opinion about the effectiveness of the compliance program of Defendant, Gilead Sciences, Inc. (hereinafter "Gilead" or "the Company") with respect to the Speaker Programs and Roundtables, (collectively, "Speaker Programs") and Advisory Boards ("Ad Boards"), which Gilead conducted from January 2013 through December 2019 (the "Review Period") for its two Hepatitis B Virus ("HBV") drugs, Viread and Vemlidy. An effective compliance program is one that prevents and detects fraud and misconduct.[1]

This report explains the criteria and methodology I used for my review, and provides a summary of my findings.

II. QUALIFICATIONS

I served for over 25 years as a federal prosecutor; eight years in the Eastern District of Louisiana in the Organized Crime Section of the Department of Justice, three years in the Eastern District of New York, and the last 15 years in the District of Maryland where I ran the Health Care Fraud Group and served as Chief of the Civil Division. In 2005, I left federal practice for health care consulting, first working for KPMG, and later, for Daylight Forensic & Advisory,

[1] See Evaluation of Corporate Compliance Programs, U.S. Department of Justice, Criminal Division, April 2019; https://www.justice.gov/criminal-fraud/page/file/937501/download and Compliance Guidance, Office of Inspector General, Department of Health and Human Services; https://www.oig.hhs.gov/compliance/compliance-guidance/index.asp.

LLC. I managed several Independent Review Organization engagements for health care clients under Corporate Integrity Agreements, conducted compliance risk assessments and internal investigations, and worked with Audit Committees and Internal Audit Departments of large health care providers including hospitals, insurers, a national retail pharmacy chain, and an international pharmaceutical company.

In 2010, I joined Ober | Kaler as a partner in its Health Law practice focusing on white collar and regulatory defense. I represented health care providers under civil and criminal investigation and expanded my role as a compliance resource for a variety of clients, including a pharmaceutical company, a generic drug manufacturer, several physician practices, laboratories, hospitals and institutional providers. I wrote compliance policies for many clients and reviewed policies for others. I also negotiated settlements with state and federal health care agencies in False Claims Act, U.S. Food and Drug Administration ("FDA"), and other health care cases. In addition, I represented individuals in health care matters in federal court, before the grand jury, and in an exclusion appeal before the U.S. Department of Health and Human Services ("HHS").

In 2012, I relocated to Charlottesville, Virginia, and began working for Centra Health, a four-hospital system as its Vice President, Compliance Officer and General Counsel. The Compliance and Legal Departments were split in

early 2015, and I served as Compliance Officer until November 2015 when I left to start my own consulting business and legal practice.

From 2016 through the present, I have worked on several matters as a compliance expert, including serving as an expert in two False Claims Act matters in U.S. District Court in the Southern District of New York involving pharmaceutical manufacturers, one expert engagement in the District of New Jersey, and serving as compliance counsel in a matter involving a non-profit health care provider. I also am currently employed by ThomsonReuters, Practical Law, as a Senior Legal Editor for their Health Care & Life Sciences legal journal which went to publication in November 2020. I continue to write, edit, and maintain health care and life sciences resources for ThomsonReuters.

I am a Vice Chair of the American Bar Association ("ABA") Health Law and Policy Coordinating Committee, a member of the ABA Health Care Litigation and Risk Management Interest Group, Vice Chair of the Life Sciences Leadership group for the American Health Law Association, and a member of the Health Care Compliance Association. I am certified in Health Care Research Compliance and am a member of the bar in New York, Pennsylvania, Maryland, Louisiana and Virginia. My CV is attached hereto as Appendix A.

For my services on this project, I am billing $400 per hour. My compensation is not dependent on my testimony or the outcome of this case. My work is ongoing, and I reserve the right to modify or supplement my opinions

and conclusions as additional information becomes available to me, or as I perform further analysis.

III. SCOPE OF REVIEW

To gain an understanding of Gilead's compliance program in the context of its Speaker Programs and Ad Board, during the Review Period, I reviewed deposition testimony, as well as documents and other information produced by Gilead, Relators and third parties pertinent to Gilead's compliance practices, policies and procedures. My review included, but was not limited to, the following:

- Gilead's Business Conduct Manuals on Speaker Programs, speaker selection and training, and Ad Boards, and other business rules, promotional policies, compliance policies and procedures from 2013 through 2019.
- Internal e-mails and other communications relating to Gilead's Speaker Programs and Ad Boards.
- Polaris Summary reports of Speaker Program reviews and audits conducted by Polaris and Gilead.
- Reports and presentation materials including training materials.
- Opinion Leader Program ("OLP") spreadsheets, materials, honoraria reports, and other information from Gilead's document production.
- Transcripts of depositions of witnesses and associated exhibits.
- Other internal review reports.
- Third party reports and spreadsheets.
- Reports to senior management.
- Gilead's responses to discovery requests.

A comprehensive list of the information I considered is provided in Appendix B.

IV. CRITERIA FOR ANALYSIS

The criteria I used for my assessment of Gilead's compliance program were the seven elements of an effective compliance program outlined in the Office of Inspector General of HHS ("OIG"), Compliance Program Guidance for Pharmaceutical Manufacturers (the "OIG Guidance").[2] The OIG Guidance provides foundational practices in the healthcare and pharmaceutical industries that are designed to minimize the risks of non-compliance with state and federal laws. The OIG Guidance also offers practices designed to prevent and detect fraud in Medicare, Medicaid and other federal health care benefit programs.

In addition, I reviewed Gilead's own internal compliance policies about Speaker Programs and Ad Boards that are contained in its Business Conduct Manuals to determine if Gilead's promotional practices for Viread and Vemilidy during the Review Period complied with its own policies. I also considered applicable laws and regulations, the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals,[3] and the U.S. Sentencing Commission's Sentencing Guidelines for

[2] Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732-23733 (May 5, 2003) (the "OIG Guidance").

[3] The Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals, effective July 2002; available at www.ucsfcme.com/physician/PhRMACode.pdf ("2002 PhRMA Code"); PhRMA Code on Interactions with Health Care Professionals, revised effective January 2009, §§6-7; http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf ("2009 PhRMA Code").

Organizations ("Sentencing Guidelines"), effective on November 1, 1991, and amendments.[4] The Sentencing Guidelines for Organizations pre-date and form the basis for the OIG Guidance. They incorporate the preventive and deterrent aspects of an effective compliance program that are applicable to all corporations.

To understand the importance of the OIG Guidance, in 2001, the OIG sought recommendations from pharmaceutical manufacturers for compliance guidance. The OIG encouraged the industry's adoption of internal controls to ensure adherence to statutes, regulations and program requirements.[5] The OIG Guidance was published in May 2003 and revised in 2009.

The OIG Guidance lists seven basic elements fundamental to an effective compliance program:

1. Implementing written policies and procedures.
2. Designating a compliance officer and compliance committee.
3. Conducting effective training and education;
4. Developing effective lines of communication.
5. Conducting internal monitoring and auditing.
6. Enforcing standards through well-publicized disciplinary guidelines; and

[4] See United States Sentencing Commission, Guidelines Manual ("U.S.S.G."), May 1, 2001, Ch. 8, "Sentencing of Organizations," at https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2001/manual/CHAP8.pdf. Archived versions of the various amended Sentencing Guidelines available at https://www.ussc.gov/guidelines/archive.

[5] OIG Guidance, at 23731.

7. Responding promptly to detected problems and undertaking corrective actions.[6]

The OIG encourages pharmaceutical manufacturers to develop and implement compliance programs tailored to their own risks. However, in its Guidance, the OIG identified specific risk areas for pharmaceutical manufacturers; these include kickbacks and other forms of illegal remuneration.[7] According to the OIG, Speaker Programs and Ad Boards fall into this high-risk category.[8]

After the Guidelines were published, Congress passed the Deficit Reduction Act of 2005 and the Affordable Care Act ("ACA") in 2010, making compliance programs mandatory for health care providers that bill federal programs.[9] The Department of Justice and OIG issued additional guidance about what it means to have an "effective compliance program."[10] I reviewed the documents and deposition testimony in this case in light of the OIG's and DOJ's compliance guidance and the ACA requirements.

Speaker Programs are of such concern that, on November 16, 2020, the OIG issued a Special Fraud Alert dealing with the risks posed by Speaker

[6] *Id.* at 23732-33.

[7] *Id*. at 23732.

[8] *Id.* at 23738.

[9] See DRA of 2005; 42 U.S.C. 1305 et seq., and Affordable Care Act, 42 U.S.C. § 1395cc(j)(9)(A) (requiring compliance programs).

[10] See Evaluation of Corporate Compliance Programs, U.S. Department of Justice, Criminal Division, April 10, 2019; https://www.justice.gov/criminal-fraud/page/file/937501/download and Compliance Guidance, Office of Inspector General, Department of Health and Human Services; https://www.oig.hhs.gov/compliance-guidance/index.asp.

Programs (see OIG: Special Fraud Alert: Speaker Programs (November 16, 2020), 2020 WL 7122359)).[11] Among the list of suspect characteristics cited by the OIG as indicia of potential fraud were:

- The company sponsors Speaker Programs where little or no substantive information is actually presented;
- Alcohol is available (and free) or a meal exceeding modest value is provided to the attendees of the program;
- The Speaker Program is held at a location that is not conducive to the exchange of educational information;
- The company holds a large number of Speaker Programs on the same topic or product where there has been no recent substantive change in relevant information;
- Health Care Providers ("HCPs") attend Programs on the same or substantially the same topics more than once (either as a repeat attendee or an as attendee after being a Speaker on the same subject);
- The attendees include individuals who do not have a legitimate business reason to attend the Program including family members of the Speaker or an attendee, employees of the Speaker's own medical practice, and other individuals with no use for the information;
- The company's Sales or Marketing business units influence the selection of the Speaker or the company selects HCP Speakers or attendees based on past or expected revenue;
- The company pays the Speakers more than fair market value for the engagement or pays compensation that takes into account the volume and value of past business generated or potential future business generated by the HCPs.[12]

[11] OIG issued its last Special Fraud Alert six years ago which demonstrates how seriously OIG considers Speaker Program compliance issues. HHS OIG: Special Fraud Alert: Speaker Programs (November 16, 2020); https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlert-SpeakerPrograms.pdf.

Speaker Programs and Ad Boards involve serious risks of illegal remuneration. Payments or transfers of value by pharmaceutical manufacturers HCPs trigger potential violations under the Anti-Kickback Statute ("AKS")[13] and the False Claims Act ("FCA").[14]

If only *one purpose* of the payment or transfer of value to the health care provider is to induce the provider to prescribe the pharmaceutical company's drugs or to refer a patient for treatment covered by federal health care programs, that payment may violate these laws.[15] This principle is commonly referred to as the "one purpose rule."

The FDA has also raised concerns about Speaker Programs and Ad Boards. While the FDA recognizes the benefit of having doctors educate other prescribers about a drug's risks and benefits, it requires that promotional presentations be "fair and balanced" and not misleading.[16] Using "educational" presentations as a means to pay physicians to prescribe a drug or to reward them for doing so increases the probability that information

[13] 42 U.S.C. § 1320a-7b.

[14] 31 U.S.C. §§ 3729-3733.

[15] *United States v. Greber*, 760 F.2d 68, 69-70, 72-73 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

[16] See 2009 PhRMA Code § 6; Federal Food, Drug and Cosmetic Act, 2010 Edition, 21 U.S.C. § 352; and 21 C.F.R. § 202.1(e)(6)(an advertisement for a drug is false, lacking in fair balance or otherwise misleading if it contains a representation, not approved or permitted for use in the labeling, that a drug is better, more effective, or more useful in a broader range of conditions or patients, or has fewer or less serious side-effects than demonstrated by substantial clinical evidence).

provided by those physicians during presentations will be driven by financial incentives and be potentially misleading.[17]

V. SUMMARY OF COMPLIANCE PROGRAM REVIEW FOR THE VIREAD AND VEMLIDY SPEAKER PROGRAMS AND ADVISORY BOARDS.

Speaker Programs and Ad Boards are inherently risky marketing tools for pharmaceutical manufacturers. These types of events provide remuneration (in the form of honoraria, other payments, and meals) to HCPs who are also prospective customers of the manufacturer's products. Pharmaceutical sales representatives (called "Therapeutic Specialists" or "TSs" at Gilead) and sales managers, who typically control many aspects of Speaker Programs and Ad Boards as event planners and hosts, are compensated on meeting sales goals.[18] They are also encouraged to spend money budgeted every year on Speaker Program and Ad Boards.[19] This creates an incentive to misuse Speaker Programs and Ad Boards in ways that can violate the AKS[20] and FCA.[21] As a result, companies that undertake risky marketing activities should plan to mitigate and

[17] Engelberg, Joseph and Parsons, Christopher A. and Tefft, Nathan, Financial Conflicts of Interest in Medicine (January 26, 2014). Available at SSRN: https://ssrn.com/abstract=2297094

[18] Sales representatives at Gilead were called "Therapeutic Specialists" or "TSs." Deposition of Leilani Larson, Sept. 4, 2020, 46:12-21; Deposition of Catherine Chan, April 29, 2021, 58:22-59:6 (compensation and bonuses were based on the prescription writing habits of providers in her territory).

[19] Deposition of Tana Sarntinoranont, Aug. 27, 2020, 160:4-21, 161:1-17; Deposition of Jay Cummings, March 9, 2021, Ex. 18, GP 00039342, HBV 2018 Goals and Objectives for Therapeutic Specialists (Speaker Programs); Chan Dep. 74:23-75:14 (all TSs requested increase in budget for speaker programs and she could not remember such a request ever being denied).

[20] 42 U.S.C. §1320a-7b(b).

[21] 42 U.S.C. §1320a-7b(g), and 31 U.S.C. §3729.

control these risks by implementing a robust and effective compliance program. In my opinion, Gilead failed to do so.

Gilead's compliance program and policies were not effective at controlling the risks created by its Viread and Vemlidy Speaker Programs and Ad Boards. In fact, it is apparent that Gilead regularly failed to conduct the Viread or Vemlidy Speaker Programs in compliance with its own policies. Gilead did not meet the standards for Speaker Programs and Ad Boards outlined in the FDA rules, OIG Guidance, or the PhRMA Code. I have reached the findings and conclusions herein to a reasonable degree of certainty in the field of health care compliance.

Findings of Compliance Failures

- Gilead's compliance program did not prevent the sales force from selecting Speakers and Ad Board participants for Viread and Vemlidy based, in part, on their prescription volumes;
- Gilead's compliance program did not reduce the risk that the Speaker presentation content was highly repetitive, diminishing the educational value of the Speaker Programs and the business need for the Programs;
- Gilead's compliance program did not prevent Sales and Marketing from using the Ad Board programs to promote Viread and Vemlidy;
- Gilead's compliance program did not prevent repeat attendance at the Speaker Programs and Ad Boards, or attendance at the Speaker Programs by other Speakers who were trained on the program content;
- Gilead's compliance program did not prevent family members or non-prescribing individuals who were not health care professionals ("HCPs") from attending the Speaker Programs, even though Gilead's Business Conduct Manual specifically states that only prescribers should attend Speaker Programs;

- Gilead's compliance program did not prevent the Speaker Programs from being social events because the presentation of educational content was merely a fraction of the whole promotional event;

- Gilead violated its own Fair Market Value policy by paying Speakers' honoraria based on a program length of two hours when, in fact, the scientific and clinical presentation was only a portion of the overall program's length; and

- Gilead's compliance program did not prevent offering Speakers and Advisors lavish meals and alcohol, or scheduling Speaker Programs and Ad Board meetings at high-end venues and other venues that provided a dining or entertainment experience;

- Gilead failed to effectively communicate the findings of and remedial actions taken in response to investigations of Speaker Program and Ad Board violations to its sales managers and TSs; instead, it conducted those investigations in secret and had no policy to ensure that the results of those investigations were communicated or used to enhance the compliance program;

- When Gilead was advised of serious issues within its Speaker Programs by third parties, it failed to take effective remedial actions to address those compliance issues.

. . .

I address each of the seven elements of an effective compliance program described in the OIG Guidance below, as the element relates to Gilead's Speaker Program.[22]

[22] The case *U.S. ex. rel. Arnstein v. Teva Pharmaceuticals, Inc.*, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019) is highly instructive here. In *Teva*, the court denied Teva's motion for summary judgment made against the relators' claim under the Anti-Kickback Statute regarding Teva's Speaker Program. The facts in the present case are strikingly similar to the facts in *Teva*. The factors relevant to the Court's analysis in *Teva* are present here and discussed below.

VI. METHODOLOGY OF REVIEW AND ANALYSIS OF GILEAD'S COMPLIANCE PROGRAM FOR THE VIREAD AND VEMLIDY SPEAKER PROGRAMS AND ADVISORY BOARD MEETINGS.

A. THE OIG GUIDANCE

I applied the OIG's seven elements of an effective compliance program to analyze the effectiveness of Gilead's compliance program for the Viread and Vemlidy Speaker Programs and Ad Board meetings it conducted during the Review Period.

B. WRITTEN POLICIES AND PROCEDURES

The OIG Guidance recommends that pharmaceutical manufacturers draft and implement written compliance policies to guide their daily operations. The policies are typically developed with the Compliance Officer's supervision, and distributed to employees, agents or contractors who provide services billed to federal health care benefit programs.[23] In addition to a core statement of ethical and compliance principles called the "Code of Conduct,"[24] the OIG recommends that pharmaceutical manufacturers develop written compliance policies addressing specific risk areas.[25]

Compliance policies must be risk-based to be effective. This means the compliance department, or its designee, should analyze risks inherent in company operations and use the results to draft its compliance policies. This

[23] OIG Guidance, at 23731, 23733.

[24] *Id.* at 23733.

[25] *Id.*

process is called a "compliance risk assessment." The company's compliance risk assessment is often supplemented by external references like the PhRMA Code, OIG Guidance or Fraud Alerts, case law, regulatory developments and agency audit plans. A risk assessment should be conducted at least annually, and the compliance policies reviewed in light of developing risks.

I reviewed Gilead's Business Conduct Manual ("BCMs") to determine if it contained policies that would prevent and detect misconduct like using Speaker Programs and Ad Boards to influence or induce physicians to prescribe Viread and Vemlidy. I also reviewed whether Gilead's compliance policies were risk-based, and whether they were updated to include existing and newly discovered risks, such as the practice of paying Speakers to speak at programs without any legitimate business need for the program, repetitive attendance at programs, and the failure to exclude as attendees inappropriate individuals like guests, spouses, or non-prescribers.

I reviewed Gilead's materials to determine if it used a compliance risk assessment to drive policy development but did not find an organized process to assess Speaker Programs and Ad Board risks. Instead, it is apparent based upon the manner in which Gilead operated its compliance program, I concluded that to the extent Gilead took any actions to reduce the risks of Speaker Programs and Ad Boards were misused, those actions were ineffectual and reactive, as opposed to proactive. Gilead engaged in virtually no meaningful risk assessment activities to drive its policy development.

From 2013 to 2019, Gilead used and published to employees an annual BCM to address compliance with respect to Speaker Programs and Ad Boards. This was available to employees in hard copy and, at a certain point, in electronic form.

Findings:

- **Although Gilead had written policies in its BCMs during the Review Period that addressed some risks raised by Speaker Programs and Ad Boards, its compliance policies were not effectively implemented, communicated or enforced.**
- **Gilead's use of Speaker Programs and Ad Boards to promote Viread and Vemlidy contradicted its BCM compliance policies, which were not followed in practice.**

The OIG Guidance identifies, as a specific risk area, relationships between sales employees and HCPs who can make or influence the referral, order, or prescription of drugs paid for by the government.[26] In addition, the OIG guidance states that when a manufacturer provides something of value to an HCP who may then prescribe the manufacturer's product, the company must consider whether it is providing a valuable tangible benefit to the HCP with the intent to induce or reward referrals.[27]

Because remunerative relationships with physicians implicate the AKS, compliance policies should be designed to detect and prevent AKS liability.[28] In my analysis, I focused on Gilead's General Compliance, Speaker Program, and

[26] OIG Guidance, at 23737-38.

[27] *Id.* at 23737.

[28] *Id.* at 23738.

Ad Board policies that would prevent and detect the use of Speaker Programs and Ad Boards to influence physicians to prescribe Viread and Vemlidy, or to reward physicians for prescribing these drugs.

- **Gilead's General Compliance Policies**

My review first focused on whether Gilead's general compliance policies effectively prevented using Speaker Programs and Ad Boards to influence physicians' prescribing behavior by paying or rewarding participants to prescribe Viread and Vemlidy. These policies include a compliance program overview, an overview of relevant laws, regulations, and industry guidelines, rules involving record-keeping, how to report breaches of compliance, and the potential discipline for violating compliance policies. In addition, Gilead's general compliance policies and related resources cite the AKS, federal and state false claims laws, FDA laws, the PhRMA Code, and other industry guidance around Speaker Programs and Ad Boards.

The framework of the general compliance policies included:

- A general commitment to the Code of Ethics and lawful business conduct:
  - a shared responsibility for compliance; and
  - an expectation that management would be familiar with laws, regulations, and Gilead policies regarding interaction with HCPs, and train and oversee their direct reports.
- A statement that the BCM applied to all Gilead personnel including management and agents interacting with HCPs.
- A statement that Gilead's promotional activities should be consistent with FDA requirements.

- General statements about prohibitions on Gilead personnel from providing anything of value to HCPs to induce them to recommend, prescribe, use, or purchase a Gilead product.
- How to report policy violations including through an anonymous hotline.
- A non-retaliation policy for reporting violations in good faith.
- A statement about potential discipline for violations of Gilead compliance policies.
- Record-keeping policies.
- Policies about conflicts of interest.

Each BCM also included an overview of relevant laws, regulations, and industry guidance including the AKS, state and federal FCA, the PhRMA Code, the OIG Guidelines for Compliance Program for Pharmaceutical Manufacturers, and the Federal Sentencing Guidelines.[29] The BCMs from 2013 through 2019 also included important language about their scope, stating that the compliance policies applied to all Gilead officers, directors, employees and agents working on behalf of the company.[30] While Gilead's general compliance policies appear to be facially adequate,[31] they were not consistently followed, or were frequently ignored, in practice.

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[29] See, for example, 2014 Gilead Business Conduct Manual, Gilead_Purcell ("GP") 00000178-184.

[30] See, for example, 2013 Gilead Business Conduct Manual, GP 0000009; 2014 Gilead Business Conduct Manual, GP 00000171; 2015 Gilead Business Conduct Manual, GP 00000493; 2016 Gilead Business Conduct Manual, GP 00000337; 2017 Gilead Business Conduct Manual, GP 00000646; 2018 Gilead Business Conduct Manual, GP 00000876; 2019 Gilead Business Conduct Manual, GP 00327026.

[31] See, for example, 2013 Gilead Business Conduct Manual, GP 00000016; 2014 Gilead Business Conduct Manual, GP 00000171; 2018 Gilead Business Conduct Manual, GP 00000869; 2017 Gilead Compliant Procedure and Non-Retaliation Policy, GP 00277965-968; 2017 Gilead Code of Ethics, GP 00277957-64; "Leading the Way", Business Conduct Update, HBV Sales

For instance, the BCMs governed how Gilead personnel should interact with HCPs when conducting sales, marketing, educational, and other activities. When discussing HCPs in general terms, the BCMs and other Gilead materials defined HCPs as persons who were part of the "continuum of patient care" with an unequivocal caveat: "***Unless otherwise specified throughout these policies***, 'HCPs' include persons who are a part of the continuum of patient care, including but not limited to physicians, nurse practitioners, physician assistants, nurses, pharmacists, laboratory and other medical technicians, counselors, case managers, treatment educators, and executives responsible for decision-making within hospitals, clinics, pharmacies, and managed care entities. ***HCPs do not include medical office staff who are not involved in patient care (such as receptionists and billing clerks) or other persons including patients, family members and other volunteer caregivers, and other members of the community."*** (Emphasis added).[32] However, when discussing Speaker Programs and other promotional events, the BCMs set forth a much narrower definition of HCPs to describe who qualified as appropriate attendees of the event. For

Meeting, (April 4, 2017), GP 00216564; Business Conduct Update, 2017 National Meeting, Silician, GP 00132790, GP 00132795 (AKS applies to "employees, HCPs, pharmacies, patients," and prohibits anything of value including "speaker/advisor honoraria, grant payments, research funding, etc.", and "meals, gifts, entertainment, favors, back-office services, increased business," "in return for"… "some intentional connection ("one purpose")"… like "prescribing, recommending" "Gilead drugs.").

[32] GP 00000009-10; GP 00000171-72; GP 00000493-94; GP 00000337-38; GP 00000646-47; GP 00000876-77; GP 00327026-27. Gilead's definitions of HCPs remained materially unchanged throughout the Review Period. See Deposition of Gilead's 30(b)(6) Representative, Erica Chien, April 29, 2021 (Day 1), 44:1-7.

instance, Section 3.1 of Gilead's BCMs limits the HCPs who should be permitted to attend Speaker Programs and other promotional programs: "All presentations, statements, and information about Gilead products disseminated through promotional activities must be consistent with the FDA approved product labeling ("on-label") ***and targeted to HCPs who are reasonably likely to prescribe the relevant product for an FDA-approved use***." (Emphasis added.)[33]

In addition, Gilead's BCM policies regarding "Invitations for Speaker Programs" affirmatively state that invitations "[m]ay be distributed only to ***those HCPs who by the nature of their practice area are likely to prescribe the product(s)*** being promoted for on-label uses." (Emphasis added.)[34] As a result, it is abundantly clear in Gilead's own written policies that only HCPs who, by the nature of their practice area, were likely to prescribe Viread or Vemlidy should have been in attendance at Gilead's Speaker Programs.[35]

In violation of its own policies, however, Gilead allowed virtually anyone in the "continuum of care" to attend its Speaker Programs for Viread and Vemlidy. This was true even though many of these individuals could not possibly prescribe the drugs at issue, or treat the underlying disease, and did not even

[33] GP 00000010; GP 00000172; GP 00000494; GP 00000338; GP 00000647; GP 00000877; GP 00327027.

[34] See Section 2.3 of Gilead's Speaker Program Policies. GP 00000084; GP 00000246; GP 00000558; GP 00000402-403; GP 00000710-711; GP 00000948-49; GP 00327103.

[35] The language in the BCMs was the official Gilead policy regarding the appropriate manner in which Speaker Programs were to be conducted. See Chien Dep. (Day 1) 32:7-10 (there were on unwritten rules related to speaker programs for Viread and Vemlidy during the Review Period); 26:10-14 (BCM was the primary document that containing and governing the policies, procedures and practices governing speaker programs and Ad Boards.)

meet Gilead's own definition of HCPs, which explicitly excluded medical office staff and others who were not involved in patient care, such as receptionists and billing clerks.[36]

In order to have as many attendees as possible at Speaker Programs, Gilead's expansive definition of individuals within the "continuum of care" was extraordinarily broad and included doctors who were not likely to prescribe HBV drugs such as radiologists, anesthesiologists, dentists and ophthalmologists. Gilead included many other inappropriate attendees as within the continuum of care like insurance company employees, office managers, and students.[37]

I reviewed testimony of non-compliance by Gilead sales employees who tried to explain how a receptionist, a billing clerk, and an administrative staff member qualified as an appropriate attendee.[38] The BCMs, however, make it clear that these are not appropriate speaker program attendees. Despite the clear definitional exclusion in its BCM policies, Gilead HBV employees invited many of these inappropriate attendees to speaker programs. The Gilead sales personnel testified at depositions that Hepatitis B disproportionately affects the Asian community, and that therefore, receptionists or billing staff should be

[36] See, for example, 2013 Gilead Business Conduct Manual, GP 00000009-10; Chan Dep. 264:20-25,265:6-12, 265:20-266:2, 273:5-13, 273:22-274:19, 275:25-276:10, 278:19-281:22, 284:4-285:23. See also Pan Dep. 23:7-25:19, 69:22-70:19, 216:23-218:4.

[37] Chan Dep. 121:15-23, 125:2-5; 124:15-25; 237:4-9; 180:5-181:22; 100:9-102:10; 280:6-280:13.

[38] See Graham Warden Deposition, September 23, 2020, 72:8-75:1, 79:7-17. See also, Deposition of Jay Cummings, March 9, 2021, 23:4-15, 28:1-5, 32:5-22, 33:8-18 (defining appropriate attendees as "customers"… "anyone who touches the patient" as within the continuum of care. A receptionist could come to a Speaker Program if "patient focused.").

included in the continuum of care for cultural reasons.[39] In one instance, Gilead sales representative, Graham Warden, testified that regional managers and directors directed that per Gilead's compliance department ("Business Conduct"), receptionists and billing clerks were within the continuum of care and thus were appropriate attendees for Gilead's Speaker Programs.[40] I have found no document or reference in Gilead's BCMs that support this testimony or the erroneous interpretation that receptionists and billing clerks were appropriate attendees for a Speaker Program aimed at imparting scientific and medical information about the risks and benefits of Viread or Vemlidy to fellow prescribers.

During the monitoring of Gilead Speaker events by Gilead's outside consultant, Polaris Management Partners, LLC ("Polaris"), remarked about the significant number of inappropriate attendees, including guests and office staff, on a number of occasions, which is notable since Gilead did not engage in a significant level of third-party monitoring. While Gilead's own policies excludes these individuals from the definition of appropriate attendees and indicate that only HCPs who are, by the nature of their practice, likely to prescribe the drugs are appropriate attendees,[41] these inappropriate attendees, including on many

[39] *Id.*

[40] Warden Dep. 323:6-325:11.

[41] See for example, 2016 Gilead Business Conduct Manual, GP 00000337-38; 2018 Gilead Business Conduct Manual, GP 00000876-77.

occasions the office staff and spouses of the speakers, were nevertheless allowed by the therapeutic specialists to attend programs.

Allowing inappropriate attendees at the Speaker Programs is an example of Gilead's "mixed messaging." The compliance policy (and Polaris) stated one thing, but Gilead did not enforce its policies for Speaker Programs. Instead, TSs often invited or allowed non-prescribers to attend Speaker Program dinners.[42] This lack of enforcement occurred at the highest levels of the HBV organization; Leilani Larson, Gilead's Senior Director of Hepatitis B Marketing who was responsible for Speaker Programs during the Review Period, testified that a receptionist was within the "continuum of care," contrary to the explicit language of Gilead's compliance policy. Ms. Larson either recklessly or willfully ignored the fact that only prescribers were permitted to attend Speaker Programs under the plain meaning of Gilead's written policies.[43]

Based on my review of deposition testimony and documents, it also appears that there was a high degree of compartmentalization or separation of the Business Conduct department from the actual Sales and Marketing operations, and the failure to conduct any systematic compliance risk assessment of the Viread and Vemlidy Speaker Programs impeded the effectiveness of the compliance policies.

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[42] See, for example, Chan Dep. 264:20-25,265:6-12, 265:20-266:2, 273:5-13, 273:22-274:19, 275:25-276:10, 278:19-281:22, 284:4-285:23; Warden Dep. 210:8-214:15.

[43] Leilani Larson's testimony that receptionists could be an appropriate attendee for Speaker Programs because they were within the "continuum of care" plainly contradicts Gilead policies to the contrary; Larson Dep. 60:20-25, 61:1-62:3.

In addition, the Sales and Marketing business goals took priority over compliance policies. Speaker Programs and Ad Boards were part of an overall, organized strategy in the Hepatitis B franchise. Sales and Marketing referred to this strategy to as "OLP" or "Opinion Leader Programming."[44] It was planned, systematic, and took place over the entire Review Period.

For example, failure to follow the compliance policies about Speaker Programs had few negative consequences apart from the TSs being required to report the noncompliance and occasional coaching by management. In addition, successful Therapeutic Specialists and marketing staff would rarely be disciplined for failing to abide by the compliance policies. There was also no evidence of TSs being disciplined for inviting inappropriate attendees or for meal spend overages. This rendered the compliance policies "toothless." While there was evidence that Gilead managers occasionally coached the TSs, almost exclusively on the issue of meal overages, I did not find a pattern of consistent discipline for breach of compliance policies.[45]

Similarly, the only examples about Speakers being disciplined for failure to follow Gilead policies was when the Speaker did not complete the training to

[44] Leilani Larson Dep. 97: 8-25.

[45] For example, Leilani Larson testified in her deposition that she was disturbed by Kimberly Groome in 2017 stating in an email that "Marissa" would be grateful for a Seattle Ad Board used to increase her Vemlidy sales. However, Larson did not report this communication to Business Conduct (the Compliance department) as required by the Business Conduct Manual or otherwise discipline Groome (Larson Dep. 153:10-20); see also 2017 Gilead Business Conduct Manual; GP 00000639-647 (Gilead personnel are expected to report actual or suspected violations of Gilead policies).

serve as a Speaker (community speaker), I found no evidence of any Speaker being disciplined for spending minimal time on the slides, or skipping slides.[46] To the contrary, the Sales and Marketing approach with the Speaker prescribers was to do what it took to keep them happy.[47]

C. Meals and Gifts

Each BCM included a section on Meals and Gifts, a subsection of which contained policies about meals at Speaker Programs, a section on Ad Boards, a section on Speaker Selection and Training, and a section on Speaker Programs. For example, the section on Meals and Gifts provided that:

- Gilead personnel may not offer anything of value (including meals) with the intent of directly or indirectly influencing or encouraging the recipient to prescribe or recommend a Gilead product or as a reward for previously doing so.
- Meals must be modest and only provided on an occasional basis.
- Meals must be provided in connection with a legitimate business purpose, that is:
    - informing HCPs about the risks and benefits of Gilead products;
    - providing scientific and educational information to HCPs;
    - receiving bona fide advisory, research, or marketing services from an HCP under an agreement; or
    - a senior executive seeking advice from HCPs and discussing Gilead's future research.
- HCPs may receive no more than $2,000 in meals and other items of value from Gilead.

[46] See Deposition of Calvin Pan, April 22, 2021, 170:22-171:19.

[47] See GP 00191854

- Guests, spouses, or significant others should not be invited to Gilead-sponsored meals. If uninvited guests show up, they may attend the function, but Gilead shall not pay for their meals or beverage.[48]
- The maximum expense limit per HCP for dinners outside of the office was $125 inclusive of food, drink, tax, parking, and gratuities.[49]

Gilead's Meals and Gifts policies generally re-stated the standards set by federal law, PhRMA, and the HHS OIG guidance. Meals for HCPs should be modest, occasional, and for a legitimate business purpose. However, Gilead personnel did not follow this core message. Instead, Speaker Programs appeared to be a way for Gilead to offer lavish meals and social gatherings for attendees and speakers. Gilead did not have a formal policy describing what constituted an "occasional" meal, (as endorsed by the PhRMA Code), and there was no systematic tracking of the amount spent for meals and beverages for attendees on an annual basis.[50]

For example, on June 18, 2015, Dr. Janjua Li, was the speaker at a Gilead speaker program held at a restaurant in New York, New York owned by one of the program attendees, Dr. Yong Kang He. There were 13 attendees at this speaker program, including two wives of attendees and five office assistants. According to the Polaris monitor who observed the program, all of the attendees were from the same practice, and the presentation portion lasted

[48] See, for example, 2014 Gilead Business Conduct Manual, GP 00000205-206.

[49] See, for example, 2016 Gilead Business Conduct Manual, GP 00000370-371.

[50] Chien Dep. (Day 2) 11:5-11; 14; 9-14.

only 30 minutes, while the meal and post meal portion lasted many hours.[51] Under Gilead's own BCM policies, seven of the attendees were not HCPs likely to prescribe for the FDA approved use of Viread, and were, thus, not appropriate attendees.[52]

A dinner program hosted by Catherine Chan at the Palm Restaurant in New York on July 7, 2016 featured 6-pound lobsters and $100 steaks. In addition to the speaker, Dr. Fufu He, the event was attended by 12 people, including one doctor, Dr. Raymond Chan, who attended with his wife, Lily.[53]

At a dinner Speaker Program held in Hacienda, California on June 22, 2017, Dr. Casey Fu-Liu was the speaker and his presentation lasted only 25 minutes with ten minutes for questions, while the meal and post meal portion of the evening took place over three hours. One physician arrived when the presentation was nearly over, and five of the HCPs worked in the same practice.[54]

There was another Speaker Program on November 17, 2017, that was held at the Toro restaurant at the Intercontinental Hotel in Miami. The Polaris monitor observing the program noted that the location was in an open area making the

[51] See 2015 Monitoring Spreadsheet, meeting 8040056, GP 00006183.

[52] There is no question that Speaker Programs regularly included attendees who were not likely to prescribe HBV drugs, including many attendees who were not legally permitted to write prescriptions at all. Chan Dep. 102:20-105:25, 112:11-113:25, 121:24-126:9, 131:3-134:18, 147:15-151:7, 173:22-266:2 (detailing dozens of instances of attendees at Speaker Program events who were not likely to prescribe HBV drugs).

[53] See IQV-Gilead 036203; IQV-Gilead 070682; Chan Dep. 232:10-13.

[54] See 2017 Monitoring Spreadsheet, meeting 0005392, GP 00006188-89.

presentation difficult to hear. Approximately 16 people attended this program and were seated at two long tables; one attendee was the spouse and office manager of one of the physician attendees. The presentation lasted approximately 1/2 hour and the dinner lasted about one hour. The monitor noted that the attendees engaged in office talk and social mingling.[55]

Despite these issues being identified by Polaris, the record shows inappropriate attendees continued to frequently attend programs, demonstrating that Gilead's speaker program dinners were in large part for social gatherings for the attendees, and not primarily for imparting scientific or medical information designed to aid the HCPs' patients.

By way of further example, at Dr. Calvin Pan's Speaker Programs numerous repetitive attendees included his paid office staff (non-prescribers), and an anesthesiologist (non-prescriber), as well as part-time individuals who infrequently worked in his office and who were neither in his employ nor prescribers.[56] Although Gilead's BCM policies stated that the meals were supposed to be modest by local standards, there were many examples where the meals exceeded Gilead's per HCP meal spend limits.[57] However, I did not

[55] See 2017 Monitoring Spreadsheet, meeting 0009319, GP 0006198.

[56] Pan Dep. 69:1-25; 70:12-16; 72:1-8; 201:8-16; 202:7-205:25; IQV-Gilead 068318 Pan. Ex. 12; Pan Dep 210:1-211:19; IQV-Gilead 065914 Pan Ex. 13.

[57] For example, an outside vendor reported that a "special Kosher meal" served to an HBV Ad Board member at Avilla Vicencio in New York on May 5, 2019 was $206.21 (65% above the $125 spending limit); another dinner at the Raymond Restaurant on April 2, 2019, was $274.71 (119% above the spending limit); a lunch at Il Piccolino on November 15, 2019 was $59.82 (above the lunch spending limit). GP 00308702-706, GP 00311269, GP 003211291, GP 00321307.

find consistent evidence of managers effectively or significantly disciplining the TSs for overages, and did not see management referrals to the Business Conduct department for further review and corrective actions.

D. Policies on Ad Board Participant Selection and Speaker Selection

Selection as a Speaker or participant on an Ad Board results in a financial benefit for the Advisor physician or Speaker who is typically also a prescribing HCP. In addition to a financial benefit, status as a Speaker or membership on an Ad Board is sought after by physicians and other prescribers.[58] The BCM compliance policies recognized this. However, the TSs and their managers were encouraged to identify potential Speakers, and even recommend participants for Ad Boards.[59] This created an incentive for Sales and Marketing personnel to keep potential prescribers happy by providing a financial as well as reputational benefit in making them Speakers and/or Ad Board participants.

To address potential risk issues with Speaker selection, the PhRMA Code offers mitigation strategies. For example, Speaker selection criteria should be in writing and based on the educational reason for the program.[60] Speaker selection itself should be based on medical expertise directly related to the subject drug or condition.[61] The number of Speakers should be limited to those

[58] Sarntinoranont Dep. 301:19-21 ("… for many people, it's an honor, you know, to be part of this speaker bureau.")

[59] Warden Dep. 50:19-54:19; see also Larson Dep. 167:22-168:19, Ex. 12, GP 00039924.

[60] 2002 PhRMA Code, pp. 4-5; 2009 PhRMA Code, pp. 7-10.

[61] 2002 PhRMA Code, pp. 3-4.

necessary to convey the information sought.[62] The Speaker's performance should be evaluated to determine if they are fulfilling their educational role, not whether they are increasing or maintaining prescription volume.[63]

The PhRMA Code also offers guidance about selection criteria for consultants and Ad Board participants. For example, Ad Board membership or participation should not be used to justify compensating health care professionals for their unrelated time, travel, or other expenses. The criteria for selecting consultants must be directly related to the identified purpose for the Ad Board, and the person responsible for selecting the consulting should have the expertise necessary to evaluate whether the particular health care professionals meet that criteria. Like Speaker Programs, the number of health care professionals retained should not be greater than the number reasonably necessary to achieve the identified purpose.

- **Ad Board Participant Selection Policies**

Gilead's BCMs included directions about selecting Advisors based on their qualifications. The BCMs stated that Sales and Marketing were not supposed to use selection to reward or induce the prescription, use, or recommendation of

[62] 2009 PhRMA Code § p. 6.

[63] See for example, HBV Business Conduct Update, Mark Andrews (2015), GP 00216626, 00216649, ("when you nominate a speaker, it is a reflection of your judgment so choose wisely." Presentation contained directions to base selection on qualifications, not sales, and critically evaluate whether each speaker is still satisfying an existing business need).

Gilead products.[64] However, in contradiction to the BCMs, Gilead conducted a return on investment analysis of the Ad Board participants and also monitored their prescribing patterns.[65] Sales and Marketing used prescribing patterns to recommend new Ad Board members and Speakers.[66] In addition, Gilead closely tracked the number of prescriptions and the market share of its Speakers.[67] Most importantly, Gilead also analyzed HCP market share data to determine which HCPs to select as participants for Ad Board meetings and how to categorize HCPs when determining whether to nominate them as Ad Board participants or Speakers.[68]

The categories that Gilead assigned to HCPs based on their prescribing habits and market share were:

- Splitters: HCPs who "split" their patient prescription between one or two drugs.[69]
- Loyalists: prescribers who prescribe one particular drug.[70]
- Dabblers: HCPs who have written prescriptions of Viread and Vemlidy, but not consistently.[71]

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[64] See, for example, 2016 Gilead Business Conduct Manual, GP 00000388-390; and Business Conduct Update and Reminders, Silician, Foster City, February 2016, GP 00132468 and GP 00132493.

[65] Larson Dep. 168:14-170:15, Ex. 12, GP 00039924.

[66] *Id.*

[67] See Larson Dep. Ex. 28, GP 00105854, March 12, 2015 email Tang to Larson (2014 sales data for current Speaker Bureau); Larson Dep. 236:16-240:1.

[68] See Larson Dep. Ex. 29, GP 00083391, May 24, 2016, Larson email to Schmalze (faculty for Ad Board to be comprised of "splitters."); Larson Dep. 244:1-245:14.

[69] See Larson Dep. 135:7-17; Sarntinoranont Dep. 67:7-11.

[70] See Larson Dep. 135:7-17; Sarntinoranont Dep. 65:5-12 (Viread Loyalist).

[71] Larson Dep. 122:16-24.

These categories for HCPs were used consistently, and by sales representatives as well as management, throughout the Sales and Marketing business units during the Review Period.

Moreover, Sales managers attended Ad Board meetings as "observers," and while they were not supposed to communicate with Ad Board participants during the actual Ad Board meetings, they reviewed what was discussed at the meetings and engaged in detailed Sales and Marketing debriefings after the meetings.[72]

The Marketing department that conducted the Ad Board meetings was responsible for developing the criteria and process for identifying and selecting advisors. However, Therapeutic Specialists could, and did, nominate Ad Board participants, even though Gilead's policies purported to prohibit such conduct.[73] The selection of individual Ad Board participants was also supposed to be approved by Business Conduct.[74]

Criteria for Ad Board participant selection should have included: clinical expertise, treatment experience with diverse demographics, research and publication experience; types of experience such as managed care, academics, community-based health care practices, private v. public health care facilities, and correctional facilities; prior positive advisory experience,

[72] Larson Dep. 74:4-25, 75:1-25.

[73] Warden Dep. 169:19-24, 170-172:1-13; Chien Dep. (Day 2)122:15-19.

[74] 2016 Gilead Business Conduct Manual, GP 00000392.

specialty practices, and level of product knowledge.[75] The number and type of Advisors were supposed to be consistent with the legitimate business purpose of the Ad Board with between 10 and 20 participants for each Ad Board session. The sessions were purportedly "designed to elicit meaningful input" and were not supposed to be used promote Gilead products.[76]

- **Gilead's Speaker Selection Policy**

Gilead's Speaker Selection and Training Policy vested Speaker Bureau development and management in the Marketing department, to be performed in cooperation with Medical Affairs, Business Conduct, Sales, and other departments. However, Marketing was responsible for identifying the Speakers, initiating and implementing the speaker training programs.[77]

Serving as a Speaker and Speaker Training each provide opportunities for physicians to receive money from pharmaceutical companies. Gilead's BCM policies recognized this risk and attempted to prohibit Speaker Selection and Training from being a means of rewarding attendees or inducing prescriptions of Gilead products.[78] Like Ad Board selection, Speaker selection was used as a

[75] 2017 Gilead Business Conduct Manual, GP 0000696-97.

[76] Business Conduct Update, 2017 National Meeting, Silician, GP 00132790, at 811.

[77] See, for example, 2016 Gilead Business Conduct Manual, GP 00000393-394; Sarntinoranont Dep. 109:17-21 (Sales representatives could nominate individuals to serve as Speakers).

[78] *Id.* at GP 00000394.

way of rewarding physicians for past prescriptions or inducing them to write future prescriptions of Viread and Vemlidy.[79]

According to the BCMs, Speakers were supposed to be selected by Marketing (with approval by Medical Affairs) based on specific criteria that included professional or personal experience, public speaking skills, and ability to lead an interactive discussion.[80] Sales personnel (TSs and managers) and Medical Scientists were encouraged to nominate Speakers.[81] Whether a HCP wrote Gilead prescriptions and the HCP's decile level were factors that Gilead could and did consider when deciding who would conduct Speaker Programs.[82] Speakers were required to conduct at least two Speaker Programs in a year (one every six months) to qualify for the training.[83] The BCMs specified

[79] Larson Dep. 182:4-185:11, Ex. 17, GP 00024142-143, email from Larson to Richardson, Nov. 13, 2013, (invite Dr. Iskandarani to Speaker training because he "receives a large number of referrals from several Haitian primary care physicians and is highly regarded among the physicians in the community." The "prevalence of HBV in Haitians is 5%. This could represent significant market growth." "Dr. Iskandarani is a 'Viread loyalist' with greater than 68% Viread market share." He "could be a strong voice for promoting its benefits." His reputation "will help getting targeted GI and hepatologists out to dinner programs."); Deposition of Chris Purcell, April 23, 2021, 471:21-472:5.

[80] Although Gilead did not allow TSs to nominate speakers because of "sales considerations," it nevertheless allowed RDs to nominate speakers, even though the RDs' compensation, like the TSs', was based on the number of prescriptions sold in their territory. Chien Dep. (Day 2) 111:2-25, 112:9-15, 113:5-9.

[81] *Id. at* 2016 Business Conduct Manual, GP 00000396; Sarntinoranont Dep. 110:4-111:14 (Sarntinoranont nominated about 24 Speakers in one year for training).

[82] Chien Dep. (Day 2) 115:16-116:17.

[83] TSs could ensure that their top prescribers remained on the speaker bureau because, during the Review Period, Gilead left the determination of whether an educational need existed to justify a Speaker Program to the discretion of its TSs. Chien Dep. (Day 2) pg. 118:19-119:18. Not surprisingly, this led to TSs holding speaking programs for the sole purpose of encouraging prescribers in their territory to write Gilead prescriptions. See Gilead TS Jane Wu requesting funds in excess of her annual Speaker Program budged because she promised additional Speaker

that Speaker Training could not be held at a resort. Live Speaker Training was supposed to take place at least once a year, but Marketing could hold refresher courses virtually with BCM approval.[84]

The purposes for the Speaker Bureau and Speaker selection were clearly outlined in the BCMs. The Speaker Bureau was supposed to train medical professionals to speak for Gilead. It was not supposed to serve as a mechanism to establish or maintain, or develop a relationship with a prescriber, or gain access to the Speaker participants.[85] Speakers were not supposed to be nominated or selected based on an implicit or explicit hope or understanding that they would prescribe, purchase, or recommend Gilead products.

For this reason, the Gilead BCMs did not allow return on investment ("ROI") analyses of Speakers.[86] However, the BCM prohibition on ROI analyses of Speakers was another example of Gilead's "mixed messaging" between compliance and Sales.

In fact, Gilead closely tracked the number of prescriptions and market share of its speakers. Gilead conducted one ROI analysis on Speaker Programs

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Programs to prescribers in her territory, without any indication of educational need for those programs. Gilead_Purcell 44925; Wu Ex. 11.

[84] *Id.* at GP 00000394.

[85] *Id.* at GP 00000396.

[86] *Id.*

during the Review Period.[87] If Gilead conducted only one ROI of the Speaker Programs during the Review Period, it did not have a meaningful way to conduct a business needs assessment that would justify the significant money spent on Speaker Programs.

Gilead tracked the prescribing habits and market share of attendees for six months before and after each Speaker Program. Despite testimony that the prescribing patterns of Speakers were not tracked, Gilead's own documents show that candidates for Speaker Programs were analyzed based on their prescribing patterns.[88] In addition, for a number of years, physicians who were Speakers could also participate in Speaker Programs as attendees. This means that when prescribing patterns of attendee physicians were tracked and analyzed, the prescribing patterns of Speakers were also captured in this data.[89]

Despite the BCM rules regarding Speaker selection, implementation of these policies appeared to be discretionary. For example, in 2014, Lelani Larson advised a Senior Manager in Internal Audit that Speaker selection was "non-traditional" during the earlier year because of a reduction in the size of the HBV

[87] Larson Dep. 236:16-240:1; 35:24-38:3 (Gilead conducted its own ROI analysis of Speaker Programs tracking prescriptions of attendees for six months before and after the program); Sarntinoranont Dep. 73:6-76:16.

[88] Larson Dep. Ex. 2, GP 00018343 (tracking Vemlidy prescriptions for potential Ad Board members in 2017); Ex. 26, GP 0105772 and 0105773, Larson Dep. 228:22-231:8 (2015 ROI analysis including attendees); Chan Dep. 43:16-44:5; 45:2-6.

[89] *Id.* Larson Dep. 232:11-25.

sales force.[90] Evidence demonstrated that Speakers were selected so that they would write more Vemlidy prescriptions.[91]

Although Gilead's policies about Speaker Selection were facially adequate, selection was certainly influenced by the Sales and Marketing teams who considered the volume of Viread and Vemlidy prescriptions written by the candidate.[92]

E. Speaker Compliance

The BCMs placed responsibility to ensure the Speaker's compliance with Gilead policies on the personnel who organize a Speaker Program (the TSs).[93] However, all Gilead personnel attending a Speaker Program were responsible for ensuring that the Speaker complied with Gilead policies. The planning on hosting employee, called the "responsible" Gilead employee, was required to report any violations of the BCM to the Marketing department (OLP) or to the Business Conduct department. Appropriate Gilead Personnel would purportedly investigate and follow-up as necessary.[94]

The only evidence I found regarding TSs reporting Speaker non-compliance was for the Speaker's failure to meet training requirements and the

[90] See Navarro email to Nelson, Sept. 26, 2014, GP 00175841.

[91] Marc Aquino Deposition, August 25, 2020, Ex. 14, GP 00025288, 216:15-25, 217:11-218:23 (Dr. Regenstein "believes in Vemlidy," but TS "is going to add him as a speaker, so when he speaks on it, he will start believing in the product even more.")

[92] GP 00007024, GP 0034371, GP 00083020, GP 00086199, GP 00167924-25, GP 00179795-97, GP 00180095-96.

[93] See, for example, 2014 Gilead Business Conduct Manual, GP 00000245.

[94] *Id.* at GP 00000250.

allegations of Mr. Sam Lee against his sales partner, Ms. Catherine Chan, in 2015 which was, as I address in detail below, not responded to appropriately.[95]

F. Policies Concerning a Bona Fide Business Need for the Speaker Programs and Ad Boards

To avoid the risk of AKS violations under the PhRMA Code, Speaker Programs or other consulting arrangements that involve payments to physicians must not be inducements or rewards for prescribing or recommending a particular medicine or course of treatment.[96] There must also be a *legitimate need* for the Speaker's or Ad Board participant's services beyond inducing prescriptions or rewarding prescribing behavior. Accordingly, the number of Speakers must not be greater than reasonably necessary to achieve the educational goals of the Speaker Program.[97] The BCM policies expressed these rules, but the concept of "business need" was flexible and driven by Sales.[98]

Gilead's BCM policies limited the number of Speakers to only those necessary to satisfy a "business need" as described in an annual Brand Plan of Action ("POA"). The "business need" was supposed to be determined by

[95] See email Kramer to Pelosi, (Sept. 20, 2016), GP 00008304 (management discussed removing Speakers from Speaker Bureau for failure to meet training requirements).

[96] 2002 PhRMA Code, pp. 4-5; 2009 PhRMA Code, pp. 7-10.

[97] 2009 PhRMA Code, § 6, p. 8; OIG Guidance, at 23737 (neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., *the purposeful inducement of business*).

[98] See Business Conduct Update, *Id.* 2017 National Meeting, Sicilian GP 00132790, GP 00132798 (presentation notes: "Elements that should be documented to establish legitimacy: appropriate venue, proper attendees, respect meal limits, commercially reasonable business purposes, appropriately tailored services, payment of FMV, speaker selection criteria").

Marketing, but Marketing relied on Therapeutic Specialists to determine the business need because they were in a "better position" to understand the needs of their geographic area.[99] Gilead TS Jane Wu acknowledged that this type of collaboration regularly occurred during her tenure as a Gilead TS.[100] This was surprising, as on the one hand Gilead left determinations of Speaker Program "business needs" to the sales representatives – while at the same time, purportedly refusing to allow the same TSs to nominate speakers because they were too close to the prescribers ("sales considerations").[101] According to the OIG's 2020 Special Fraud Alert about Speaker Programs, having the Sales and Marketing business units determine Speaker Selection is a "suspect characteristic" for potential AKS violations.[102]

Marketing managed the Speaker Programs, retained all records and documents used during the Speaker Programs, reviewed Speaker utilization, determined whether to keep a Speaker, made sure that each Speaker had a signed agreement, and determined Speaker eligibility. Speakers who

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[99] Deposition of Jeremy Schmalzle Sept. 25, 2020, 87-88:1-19, 89:5-15, 90:21-25, 91 (relied on the Sales managers, regional directors, and TSs to figure out the number of Speakers needed in a geographic area). See email from Gilead TS Jane Wu requesting money in excess of her Speaker Program budget allowance because an HCP in her territory wants to conduct additional Speaker Programs, demonstrating that TSs were not conducting any legitimate needs or educational assessment for programs, but were simply trying to make their prescribers happy to drive sales. GP 00044880; Wu Ex. 11.

[100] See GP 00045087; Wu Ex. 8; Wu Dep. 223:16-224:6.

[101] Chien Dep (Day 2) 109: 2-25.

[102] OIG: Special Fraud Alert: Speaker Programs; https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf

demonstrated poor product knowledge and presentation skills or violated Gilead policies were ineligible to serve as a Speaker.[103]

David L. Johnson, Gilead Vice President of Sales and Marketing, testified that from 2013 through 2018, Gilead had about 40 Therapeutic Specialists in the Hepatitis B franchise.[104] He explained that OLP came up with the number of Speakers needed to educate the physician population. Marketing presented the OLP program to him after supposedly working with Business Conduct to come up with the number of topics and the number of programs for both Speaker Programs and Ad Boards during budget discussions for the following year. Mr. Johnson stated that the "experts in OLP" came up with the numbers after working with compliance. Mr. Johnson then signed off on the OLP budget.[105]

The business need for the Speaker Programs for Viread and Vemlidy was expressed as an "educational" need. The "educational" need was defined by Sales and Marketing. Sales attempted to reach 4,000 "targets" annually for Hepatitis B "education."[106] TSs were required to invite a certain number of targets to each Speaker Program.

[103] GP 00000397.

[104] Deposition of David L. Johnson, August 31, 2020, 45:1-14 ("there was a discussion between marketing and legal around how many speakers were needed to educate the population of health care providers."); 58:15-59:9; Chien Dep. (Day 2)100:5-10.

[105] Johnson Dep. 42:5-25, 43:1-23, 45:1-15, 46-48:1-23.

[106] Targets were HCPs who could prescribe. Larson Dep. 81:2-21, 99:14-102:8.

"Targets" were defined as prescribers. Targets were considered separately from other attendees although they were included in the total attendee count. Therefore, the "business need" for a Speaker Program was determined to a large extent by the Therapeutic Specialists hosting the Speaker Program. At the same time, the Therapeutic Specialists had an obligation to meet target goals for compensation purposes.[107] But there was no quantitative metric to determine whether there was a "business need" for a speaker program or Speaker.[108]

Gilead Sales and Marketing tracked the prescribing patterns of the targets and whether they prescribed Gilead products or another brand.[109] Marketing would communicate this information to the Sales department which then provided the names of potential Speakers to Marketing based on information from the TSs.[110] Gilead typically offered two-year contracts to HCPs to serve as Speaker without performing an assessment of future needs. In reality,

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[107] Schmalzle Dep. 90:21-25, 91; Johnson Dep. 45:1-16, 37:18-38:19, 58:15-25 (there were about 48 TSs from 2013-2018, and during budget planning, discussed how many speaker programs were needed).

[108] Schmalzle Dep. 54:1-21 (there was no quantitative measure to determine whether there was a business need for a dinner. It "ultimately comes down to the person that's going… that's hosting the dinner."); Cummings Dep. 22:1-20 (TSs determined the educational need for a particular territory); Chien Dep Day 2 118:19-25; 119: 1-2 (Gilead did not provide TSs with a list of factors to utilize in determining whether an educational need existed to justify a speaker program).

[109] Sarntinoranont Dep. 72:15-20, 73:6-20. See also GP 00018247; Wu Ex. 9; Wu Dep. 236:13-22. GP 00045212; Wu Ex. 10; Wu Dep. 243:8-11 (Gilead Regional Sales Director asking Gilead TS Jane Wu her opinion about whether an HCP who was writing more prescriptions for competitor drugs than Gilead should be removed as a paid speaker (and whom she had identified as a "usual culprit" for writing prescriptions for competitors), which resulted in him being removed.)

[110] *Id.* 110, 111:1-15, 113:11-21, 114:1-12.

it appears that who acted as a Speaker, and how many Speaker Programs were conducted, depended on the sales needs of the TSs[111] or the desires of the Speakers and not on business or educational needs.[112] The Speaker Program was a means of increasing sales.[113]

Target attendance at the Speaker Programs did not appear to indicate a need for more programs.[114] TSs were supposed to invite two or three targets (prescribers) to each Speaker Program.[115] But in 2013, the aim was two target prescribers in attendance for a Speaker Program, and in certain geographic areas only **1.3 to 1.5 targets** actually attended Speaker Programs from January through March of 2013.[116] By April 2014, some regions still only had an average of **1.6 targets** in attendance at each Speaker Program.[117]

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[111] Gilead TS Jane Wu does not ever recall her managers rejecting even one of her recommendations regarding removing HCPs from the OLP. Wu Dep. 227:8-16.

[112] See GP 00044925; Wu Ex. 11 (Gilead TS Jane Wu requesting funds in excess of her annual Speaker Program budged because she promised additional Speaker Programs to prescribers in her territory, without any indication of educational need for those programs.)

[113] See Gilead TS Ivan Tai's Business Plan, which includes a tactic to increase the Gilead prescription writing of one of the prescribers in his territory by scheduling one Speaker Program a month for the prescriber. The Business Plan so clearly demonstrates that Mr. Tai was utilizing paid Speaker Programs to increase prescription writing of the speakers that he actually denied that he had written his own Business Plan which had been presented to his Regional Manager. Deposition of Ivan Tai, Oct. 5, 2020, 143: 2-7; 149:8-14; GP 00046969; Tai. Ex. 4; see also GP 00045428; Wu Ex. 7; Wu Dep. 220:1-5 (Monthly Sales Strategies document from Gilead TS Jane Wu indicating that one of her short term strategies to drive prescription sales was to schedule HCPs in her territory for Speaker Programs, which, although denying it was her intent, she acknowledged her words made it seem as though she wanted to use the Speaker Programs to increase the prescription writing of the speakers.)

[114] Johnson Dep. 214:8-25.

[115] *Id.* at 242:13-21, 243:1-15.

[116] Larson Dep. Ex. 3, GP 00017768, email Ebert to Wolfgang, March 25, 2013 (Target Attendance Average YTD v. 2012).

[117] Sarntinoranont Dep. 248, 249.

To remain a speaker in Gilead's Speaker Bureau, physicians needed to complete a minimum of two or three Speaker Programs per year.[118] To meet this requirement, it appears that Sales conducted the same Speaker Program as many as ten times in a quarter.[119]

The BCM Ad Board policies also required a bona fide "business need."[120] Unlike Speaker Programs, Ad Board policies stated that "an educational opportunity" or a "promotional opportunity" were not appropriate reasons for an Ad Board meeting. The Ad Board meetings were supposed to receive marketing feedback from the participants.[121]

Sales and Marketing apparently relied on internal controls to ensure an appropriate number of Ad Boards.[122] These were: requiring a request for approval ("RFA") from the Business Conduct department for the Ad Board, payments to the physicians attending the Ad Board based on fair market value, and a written contract before engagement of the Ad Board member.[123] These processes did not critically address question of whether there was a bona fide underlying need for an Ad Board.

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[118] Larson Dep. 130:1-14.

[119] Sarntinoranont Dep. 249:4-21, 250-252.

[120] *Id.* at 146:11-17.

[121] Larson Dep. 42:12-18; Sarntinoranont Dep. 147:17-21, 148:1, 150:11-21, 151:1-21, 153:1-156:6.

[122] Johnson Dep. 46:6-48:10.

[123] Larson Dep. 114:18-115:3, 50:1-8.

The Marketing Department "prioritized" invitations to Ad Boards. It is clear that the physician's prescribing history was considered. Ad Boards were used as part of a POA to market Vemlidy to physicians who were not prescribing that drug.[124]

G. Policies on Number of Attendees at Speaker Programs

The number of legitimate attendees (*i.e.*, permitted audience members) at Speaker Programs is relevant to AKS risk. The number of legitimate attendees reflects whether the manufacturer is paying for meals and honoraria incidental to legitimate prescriber education about its drugs, or instead, using Speaker Programs as a pretext for making payments to HCPs or offering benefits for illegitimate purposes (such as increasing prescriptions or rewarding high prescribers).

The BCM policies recognized this issue in principle. For example, Gilead had a policy that, if 48 hours before the Speaker Program, less than four HCPs responded positively about attending, the responsible Gilead employee was required to cancel the program.[125] However, TSs in some cases went forward with the Speaker Program despite less than four attendees.[126]

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[124] Cummings Dep. 130:13-23, Ex. 13, GP 00039788 (business planning spreadsheet with references to "user, dabbler, and nonuser")156:1-14; 164:11-165:8 (no reprimand from management for using Ad Boards as part of a POA to address physicians who were not prescribing Vemlidy).

[125] "Leading the Way," *Id.* at GP 00216594.

[126] See email from AHM to Schmalzle, December 9, 2016, GP 00166447 (roundtable with three attendees); email from AHM to Schmalzle, May 18, 2015, GP 00180689 (speaker program with 1

Gilead's enforcement of the minimum attendance policies for Speaker Programs (four attendees) and its policies about who counted as a legitimate attendee were inconsistent. The minimum attendee policies were compromised by Gilead's broad definition of an "HCP" to include non-prescribers like receptionists and billing staff as within the "continuum of care." In practice, Gilead counted family members, non-prescribers, receptionists, students, and office managers as appropriate attendees towards meeting the minimum four attendees necessary (and likely justifying the meal spend where this was a fixed amount).[127] However, according to Gilead's own BCM policies, guests, receptionists, and office staff were not legitimate attendees.[128]

This also raises the question about the true purpose of the Speaker Program. If the purpose of the Speaker Program was to provide educational, medical, and scientific information to prescribers, it is difficult to understand the purported need to invite non-prescribers like billing clerks and receptionists. These attendees did not need scientific information about the risks and benefits of the drugs to do their jobs nor were they an appropriate audience for this type of information (as confirmed by Gilead's own BCMs).

speaker and two TS); Cumming Dep. 31:21-32:4 (minimum attendance was four "customers" at Speaker Program).

[127] Larson Dep. 78:14-79:4, 79:8-13, 80:5-25.

[128] Schmalzle Dep. 58:14-25 (a billing administrator would not be an appropriate attendee unless they did something more than sending out bills).

During deposition testimony, Leilani Larson, the Senior Director of Hepatitis B Marketing, parroted the excuse that "receptionists" could be included as legitimate attendees within the "continuum of care" despite the BCM policies to the contrary.[129]

Identifying who properly counts as a "legitimate attendee" for a minimum audience requirement for Speaker Programs helps manage the risk that Therapeutic Specialists may include inappropriate attendees in the total head count, defeating the compliance purpose of the minimum attendance requirement. An example of an inappropriate attendee whom Gilead counted as a legitimate attendee would be a health care prescriber in a field of medicine that was unrelated to the clinical or therapeutic use of either Viread or Vemlidy. For example, TSs and managers apparently believed they could include an ophthalmologist, gynecologist or dermatologist in the "legitimate attendee" count, despite these specialties having no on-label reason to prescribe the product.[130]

Invitations to health care prescribers who were not involved in Hepatitis B diagnosis and treatment was inconsistent with the BCM.[131] In this regard, Sales personnel did not comply with Gilead's own policies about who counted as a

[129] Larson Dep. 61:10-24, 62:18-25, 64; and see Schmalzle Dep. 57:9-59:19, 60:1-19, 61, 62:7-25 (a receptionist could be within the continuum of care).

[130] Warden Dep. 78:10-24.

[131] *Id.* 277:9-21, 278-281 (dermatologist and student nurse).

legitimate attendee at a Speaker Program.[132] This created a significant risk of AKS violations.

In my opinion, the Speaker Program compliance policies were not effectively followed, as evidenced by the Sales and Marketing personnel, including management, allowing receptionists, non-clinical, or billing staff to attend an expensive dinner. This also falsely inflated the speaker program attendance numbers in order to conceal that the programs violated the minimum attendee compliance requirement.

H. Ineffective Repeat Attendance Policies

The BCM policies prior to 2016 failed to control for the risk that an HCP would repeatedly attend events about Viread despite the Speaker Programs not having any educational value for that HCP. Gilead also failed to mitigate the risk that the same HCP attendees would repeatedly receive something of value (meals and/or honoraria) at an event without an educational component.[133]

Gilead's repeat attendance policy was not established until 2016. This policy limited an HCP to attending three Speaker Programs per year on the

[132] See Cracking the Code to Compliance, (Nguyen), 2019 Gilead Meeting, GP 00324494 (Direction that HCPs must be in the continuum of care. No spouses or guests were to be invited. No invitations designed to influence the attendees); compare Warden Dep. 296:16-24 ("doctors, they work all day, so do nurse practitioners, PAs, *these ladies in the offices*, they have other things to do with their time besides come and listen to an educational event.")

[133] See "Leading the Way," *Id.* at GP 00216592 (attendees permitted to attend the same program topic three times per year. Speakers could only attend as a participant on their topic two times per year. "Be mindful of the perception of overall excessive attendance at Gilead speaker programs.")

same topic.[134] Gilead's Speaker Program vendor, Advanced Health Media ("AHM"), tracked the number of times an HCP attended a Speaker Program on a particular topic and provided alerts when attendees were close to this limit.[135] But when there was supposedly a new "topic" for the speaker program, the HCPs were then allowed to attend three additional speaker programs that year.[136] In addition, in 2016, there was a new policy that a Speaker could not attend any program for which they were trained as a Speaker prior to 2016, and an HCP could serve as a Speaker for a topic and also an attendee for the same topic.[137]

As with other compliance rules, Gilead pushed the responsibility for compliance onto the vendor (AHM) responsible for logistics or to the "responsible" employee (the TSs). Given that the Therapeutic Specialists and managers were compensated based in part on the number of Speaker Programs and their sales, this was an ineffective compliance control.

[134] See email from AHM to Schmalze, April 26, 2017, GP 00189400 (AHM advised that an HCP had attended three HBV Speaker Programs by April of 2017); and see email from Kevin Smith to Zlatar, June 16, 2017 (Speaker Program Update), GP 00192292.

[135] See email from Kramer to Louie, June 1, 2018, GP 00226360 (this email contains contradictory language about the number of times a Speaker could attend a program on a particular topic, allowing two programs as opposed to the "no programs" policy in 2016). It is also unclear about whether office staff who were non-prescribers, non-HCPs, and simply receptionists or billing clerks were tracked by AHM. If so, I did not find evidence of this.

[136] See email Collett to Kramer, September 25, 2007, GP 00272450.

[137] *Id.* at GP 00192293; Warden Dep. 252, 253:1-7.

In addition, Gilead allowed exceptions to this rule, so that Speakers were allowed to attend the presentations of another Speaker.[138]

TSs or AHM were responsible for confirming that Speaker Program attendees did not bring family members or non-employees to the dinners. The TSs (who were incentivized to keep the Speakers and attendees happy) and the logistical vendors (AHM) maintained attendance lists.[139] Deposition testimony indicated that TSs did not conduct a complete review of who actually attended.[140]

According to Gilead employees, the slide decks did not change much over the review period (except for the Vemlidy launch) though sometimes new or different slides were needed for the Speaker Programs to encourage attendance.[141] Until at least 2016, Speakers were attendees at other Speakers' events[142] and Gilead policies did not prevent multiple instances of repeat attendance when the Speakers and attendees were already familiar with the drugs and the speech content.

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[138] Cummings Dep. 110:12-25, 113:1-5, 113:8-24, Ex. 7, GP 00191839-840 (2017- exception to allow Speaker to attend a presentation by another Speaker).

[139] The BCMs refer to "responsible employees." See HBV Business Conduct Update, (Andrews), 2015, GP 00216626, and "Cracking the Code;" *Id.* 2019, GP 00324496.

[140] Warden Dep. 248:7-23, Ex. 19, GP 00066307-311 (noting a number of people whose job title on the attendance forms was listed as "other" without a business address); 273:3-24 (people who did not show up were included on the attendance lists but there was no signature by their names).

[141] Warden Dep. 204-206, Ex. 14, GP 00192862 ("it's practically the same deck that changes its hats and socks to look like a new one"); Warden Dep. 206:2-18.

[142] Warden Dep. 209, 210, Ex. 15, GP 00116973-876, (Dr. Martinez presented to two attendees, Dr. Bao and Dr. Chai, who were "knowledgeable about liver disease").

I. Policies on Speaker Program Venues and Modest Meals

Therapeutic Specialists' interactions with HCPs are permitted under the PhRMA Code if professional in nature and *intended to facilitate the exchange of medical or scientific information benefitting patient care*.[143] Simply entertaining healthcare professionals (or their office staff), however, serves no legitimate purpose and is purely remunerative.[144] The BCM policies stated that Speaker Program venues should be quiet and private enough (with appropriate audiovisual equipment and presentation space) for educational communication. Venues should not be lavish or suggest that dinner at a fancy restaurant is a reward or perk for the prescriber or attendees. However, at Gilead, in practice, attendees and TSs did view the Speaker Programs as "treats" and "fun" events.[145]

The BCM Speaker Program policies limiting dinners to appropriate venues were facially adequate. In practice, the Therapeutic Specialists and their managers or the third-party vendors, handled the details.[146] As with other

[143] See 2002 PhRMA Code, at p. 2 (relationships with HCPs are intended to benefit patients and to enhance the practice of medicine), p. 7 (provision of entertainment and recreational activities is inconsistent with the Code); 2009 PhRMA Code, § 3, p. 5 (Prohibition on Entertainment and Recreation).

[144] See OIG Guidance, at 23738; see also emails between Sarntinoranont, Koomey and Larson, May 2014, re: event at Innsbrook Golf and Spa Resort; GP 00269338; email between Larson and Kramer, Sept. 14, 2016, re: questions for Speaker Program Administration (indicated still dealing with speaker requests for extra compensation like flying first class, extra night stay, or use of resort and spa venues if acceptable); and GP 00140934.

[145] See "Cracking the Code," (2019), (Speaker travel should not be booked to accommodate the personal considerations of the Speaker), GP 00324496; Chan Dep. Ex. 26 CCX 0011, 269:9-270:9 (texts referring to speaker program as a "treat" and a "fun night").

[146] See "Leading the Way," at GP 00216593 (venue choice should not be driven by speaker or attendee preference).

compliance rules, Gilead allowed exceptions to the Speaker Program policies prohibiting meals at fancy venues, golf clubs, or resorts.[147] By September 2016, Gilead relaxed its rules about venues and allowed Speaker Programs at venues that had the word "casino," "country club," or "resort and spa" in their name.[148]

Providing meals to physicians is only acceptable under the PhRMA Code if the meeting is designed to impart scientific and clinical information that may lead to improved patient care, and the *meal is modest by local standards*.[149] Gilead's BCM policies limited the amount spent on Speaker Program meals; for example, dinner was not to exceed $125 inclusive of tax and gratuity.[150] Alcohol was frequently served,[151] and alcohol was included within the $125 limit. In my opinion, drinking beer or wine with dinner could not have enhanced the educational value of the Speaker Programs and in fact, made them look more social than educational.

In addition, although I am not an event or meeting planner, it would seem unnecessary to spend $125 per person for food and beverage if one was only

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[147] Larson Dep. 141:14-18, 143:7-25, 144-147; Ex. 5; GP 00269338-339.

[148] See email from Larson to Kramer, Sept. 14, 2016, re: Ralston email, (Questions for Speaker Program Administration), GP 00140934; see also email from Koomey to Larson, May 21, 2014 (allowing a meeting at the Innsbrook Golf and Spa Resort despite AHM objection), GP 00269338.

[149] 2002 PhRMA Code § 2.

[150] Johnson Dep. 153:16-25, 154; 2013 Gilead Business Conduct Manual, GP 00000044-045 ; 2014 Gilead Business Conduct Manual, GP 00000206-207; 2015 Gilead Business Conduct Manual, GP 00000526-527; 2016 Gilead Business Conduct Manual, GP 00000370-371; 2017 Gilead Business Conduct Manual, GP 00000678-679; 2018 Gilead Business Conduct Manual, GP 00000912-913; 2019 Gilead Business Conduct Manual Gilead Purcell 00327062-063; 2017 BCM Excerpts for Meeting Planners, GP 00132372- 373 (outside lunches were to be no more than $50.)

[151] See "Cracking the Code to Compliance," (Nguyen), 2019, GP 003244941 (policy of no more than two drinks per attendee).

looking to serve a modest meal. I understand that Gilead's Interrogatory responses state that its Business Conduct Group and North American Compliance Review Committee were responsible for setting the per person meal spend limits.[152] Its corporate designee also testified that the $125 limit was used consistently across the country for "simplicity of administration."[153] An effective compliance policy would have required the per person limit conform to the PhRMA Code which requires it be "modest as judged by local standards."[154]

In November 2016, Gilead apparently revisited the amount spent on meals in expensive geographies. Gilead reviewed a report regarding other pharmaceutical companies establishing a premium for meal limits for attendees at Speaker Programs. Four of the ten companies in the report had meal limits of from $125-$150 for speaker events. Six of the ten companies did not allow a higher meal allowance for more expensive locations.[155] I found no evidence that Gilead engaged in any meaningful examination or process to determine the budget necessary to serve a modest meal, as opposed to a high-end or expensive meal (in violation of the PhRMA Code), which was incorporated into

[152] Gilead's May 28, 2020 Responses and Objections to Relators' Third Set of Interrogatories.

[153] Chien Dep. (Day 2) 10:5-11:2.

[154] 2009 PhRMA Code p. 21.

[155] TGaS Advisors Premium Meal Limit Allows for Expensive Geographies, November 2016, GP 00134570.

the BCMs.[156] Indeed, many of the Speaker Programs occurred at fancy and world-renowned restaurants, such as Morimoto, Ruth's Chris, Capital Grille, and Morton's Steakhouse as well as at restaurants that offered a dining experience like Asian Jewels Seafood and Park Asia.[157]

As with other compliance issues, Gilead relied on AHM and the Therapeutic Specialists to monitor and allocate the costs per Speaker Program.[158] In some cases, the number of attendees affected the costs of each attendee's dinner (the more attendees, the lower per dinner cost). Regardless of whether the amounts actually spent on the dinners exceeded the "modest by local standards" test, the apparent lack of consequences for repeated violations of this requirement shows the compliance program was deficient in this regard.

J. Policies Around Honoraria Amounts

Compensation to an HCP for Speaker services triggers AKS risk because payments can be used to induce or reward prescribing behavior.[159] If even *one*

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[156] GP 00000042; GP 00000204; GP 00000524; GP 00000368; GP 00000676; GP 00000910; GP 00327060.

[157] See Appendix C.

[158] Business Conduct Update, 2017 National Meeting, *Id.* GP 00132802 (Gilead had a $2,000 annual limit per HCP which included all Concur expenses and AHM Speaker Program meals. If meals were over the limit, the expense was supposed to be flagged at the manager and employee level. "No shows" were not supposed to be used to add additional food and beverage to a meal); GP 00132805. However, I reviewed several spreadsheets indicating that receipts were not provided by the sales personnel, so I am not sure how this was tracked without a receipt. I also noted deposition testimony reflecting one occasion where 38 attendees at a Speaker Program were recorded, but the receipt from the Peninsula Grill showed that 43 meals were paid for. See Warden Dep. 282:1-14, 283, 284:1-17; Ex. 21 (B), GP 0048637.

[159] OIG Guidance, at 23737, 23738.

purpose for paying the HCP is to induce future prescribing, or to reward for past prescribing, the statute has been violated. Compensation in excess of FMV triggers AKS concerns.[160] To avoid this risk, pharmaceutical manufacturers must put Speaker agreements in writing; there must be a bona fide business purpose for the Speaker arrangement, the services must be performed, and compensation paid must be documented. Finally, compensation must be no more than fair market value ("FMV").

Gilead had FMV rules in its Business Conduct Manuals and used a FMV tool for evaluating compensation to Speakers and Ad Board participants. However, Gilead had an exception process in this area as well; exceptions to FMV could be approved by the Associate General Counsel of Business Conduct and the business unit vice president.[161] In order to justify the honoraria amount paid to Speakers, Gilead's FMV policy contemplated a program length of two hours. However, as Gilead's own third-party monitor Polaris noted, the medical and scientific presentation portions of programs were often a minimal portion of

[160] When a person who is in a position to control from where a Medicare patient purchases an insured item or service, is paid for that referral, not only will the medical referral decision not be made in the patient's best interests, but the overall cost of healthcare will be driven up by payment of referral fees and referral of patients for care they do not need. See "Prosecuting and Defending Health Care Fraud Cases" Michael K. Loucks and Carol C. Lam, The Bureau of National Affairs, Inc., Washington, D.C. (2003), p. 146-148. Compensation in excess of fair market value for services provided is not "commercially reasonable" and therefore raises AKS concerns. See 42 C.F.R. §§ 1001.952(d)(5), (d)(7); see also OIG Guidance, at 23737.

[161] Marketer Business Conduct Training, May 2017, GP 00132517; Johnson Dep. 160:12-25,161; Ex. 4, GP 00018335-00018336, email from Kramer to Johnson, January 2017, (five speakers on the HBV speaker bureau were approved for a FMV exception to their honoraria rate. Request for an additional approval over this increase for a Dr. Zhang).

the overall program length, undercutting the FMV justification for the honoraria paid.[162]

The PhRMA Code advises that the total amount of Speaker payments per HCP should be capped each year.[163] At Gilead, there were apparently "soft caps" and "hard caps" on honoraria. The honoraria varied for the drug being promoted. Different drugs were classified as "franchises." The honoraria caps limited how many times a Speaker could be used, but the "soft caps" could apparently be waived by a Regional Director. AHM tracked the honoraria spend.[164]

Gilead capped the Speaker Program honoraria and other payments at $100,000 per Speaker per year.[165] This was tracked by AHM and not by Gilead.[166] The $100,000 honoraria limit apparently did not include Speaker travel expenses, Speaker Training, other consulting fees, or meal costs.[167]

Generally, Gilead paid the Speakers about $1,500 to $4,500 per speech.[168] To appreciate the frequency and extent of these payments, it is helpful to

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[162] GP 00000802 at 821; see also Chien Dep. (Day 2) 43:13-44:5 (Gilead understood that the slide deck presentation and question and answer session often lasted only 45 minutes to 1 hour.)

[163] 2009 PhRMA Code § 7.

[164] Email Sarntinoranont to Zlatar, Sept. 3, 2014, re: Speaker Honorarium Caps- Revised, GP 00154709.

[165] In or about 2015, however, Gilead modified its per person cap of $100,000 so that it only included speaker programs (and not, for instance, Ad Boards), thereby permitting individuals to collectively be compensated more than $100,000 a year by Gilead. Chien Dep. (Day 2) 37:10-38:21.

[166] Larson Dep. 127:12-25, 128, 125.

[167] GP 00000001, at 55.

[168] IQV-Gilead-092185.

consider that from 2013 through 2019, exclusive of travel and meals, Gilead paid its top prescribers in excess of $8.6 million in speaking fees over the Review Period, including paying 13 different physicians each $100,000 or more to conduct Speaker Programs during the Review Period.[169]

Speakers were paid honoraria even if fewer than four attendees attended a Speaker Program. When the attendance was below the minimum, Speakers were paid the honoraria anyway. For example, on or about September 13, 2017, Gilead held an HBV Speaker Program and only one attendee showed up. The Speaker was compensated for a one-on-one dinner with the sole attendee.[170]

Although Gilead may assert that the honorarium amounts paid to Speakers represented FMV for a speech, if there was ***no valid business reason*** for the payment because the Speaker Programs were social and not educational, or the attendees were largely not HBV prescribers, the payments likely violated the AKS. In addition, since the evidence indicates that the Speakers were generally presenting for less than half the time for which they were supposed to presenting in order to receive the honorarium, the evidence establishes that Gilead systemically violated its own FMV policies and overpaid its Speakers, based upon its own calculations of FMV.

[169] See Appendix D.

[170] Johnson Dep. 208-210:1-18, Ex. 13, GP 00193399, Sept. 13, 2017 email salesforce to Laura Cruz.

K. Additional Amounts Were Paid to Speakers for Ad Boards

Gilead bolstered its payments to prescribing doctors by paying the Speakers and other physicians to serve on Ad Boards. Gilead paid Ad Board attendees from $2,000 to $4,000 for each Ad Board plus travel, lodging, and expenses.[171] Unlike Speaker Programs, during the Review Period, Gilead did not have a cap on the amount an Advisor could be paid on an annual basis for participating in Ad Boards.[172] Speakers attended Ad Board meetings and these, like Speaker Programs, included a social aspect as well as marketing. Significantly, Ad Board participants attempted to recruit other physicians to attend marketing events.[173]

Gilead held several Ad Board meetings each year. Gilead typically had Ad Board meetings after every big conference.[174] Marketing held additional separately scheduled Ad Board meetings for Hepatitis B physicians.[175] Sales and Marketing employees often attended both the Ad Boards and the Speaker Programs.[176] Unlike Speaker Programs, Gilead did not engage in any third-party monitoring of Ad Boards and any internal compliance monitoring

[171] Cummings Dep. 165:1-13; Ex. 15, GP 0039790, Oct. 13, 2017 (email reflecting apparent payment of $2,000 for Dr. Simon in connection with Ad Board). GP 00006539.

[172] Chien Dep. (Day 2) 125: ln 5-9.

[173] Chang Email to Nravendhra, cc Kramer, June 5, 2016, GP 00174032.

[174] Sarntinoranont Dep. 31:13-21.

[175] *Id.* at 32.

[176] *Id.* at 36:6-15,

was minimal, at best.[177]

This relationship between Sales and Marketing, and the Ad Board nomination process created compliance risks that were recognized in the BCMs. However, these were not effectively addressed in practice. For example, Ad Boards were not supposed to be used as educational opportunities, promotional tools, or as a reward for, or to induce, prescribing behavior.[178] But Sales employees clearly understood that one way to increase their own sales of Viread or Vemlidy was to increase market share.[179] In this regard, the Sales employees' participation in the Ad Boards created a conflict with the BCM policies because they attended the meetings.

Sales managers nominated participants for an Ad Board meeting and attended the meetings "to observe."[180] Marketing conducted the Ad Board meetings, but at some point after a physician was nominated by Sales to participate in an Ad Board, and the physician accepted, the TS who nominated the physician was in the position of promoting Viread or Vemlidy to a physician who was a paid Ad Board consultant or advisor.[181]

Moreover, Sales managers who were present at the Ad Board meetings

[177] Chien Dep. (Day 2) 125:18-25, 126:22-127:7.

[178] Sarntinoranont Dep. 142:1-143:10.

[179] *Id.* at 58:18-21, 59:1-17; 78:7-17 (the sales representatives and managers were paid a salary and performance bonuses based on the amount of sales).

[180] *Id.* at 137:11-21, 138-141:1-10 (Marketing would email Sales a request for a list of nominees for the Ad Boards).

[181] *Id.* at 144:5-21, 145:1-14; 146-147.

evaluated the physicians who attended based on their participation in the Ad Board.[182] Despite the attempted distinction between Sales and Marketing, the lines between the two blurred. Sales promoted the products but also attended the Ad Boards (which were not supposed to be promotional). Like the Speaker Programs, Gilead used the Ad Boards to expand the market and develop relationships with physicians (who might then prescribe Viread or Vemlidy) through its OLP engagement project.[183] This is further supported by the fact that TSs could select Ad Board advisors until at least 2017.[184]

VII. THE BUSINESS CONDUCT (COMPLIANCE) DEPARTMENT

The second element of an effective compliance program is a Compliance Officer and department with responsibility for the Compliance program.[185] An effective compliance program includes a formal commitment by the Board of Directors and the allocation of adequate resources. A Compliance Officer with real authority is critical to a program's success. The OIG recommends that the Compliance Officer be a high-level official with direct access to the CEO, Board and legal counsel. The Compliance Officer

[182] Sarntinoranont Dep. 153:1-20.

[183] Larson Dep. Ex. 21, GP 00167934, Larson email to Zlatar, Apr. 2, 2014 (OLP spreadsheet containing names of "important customers that we should be interacting with from your regions" who are "possible faculty positions."); Larson Dep. Ex. 18, GP 00141637, Graham email to Larson, Feb. 28, 2018 (list of prescribers and meetings scheduled. Dashboard with dinner tracker, and Hepatitis B OLP Project Planner); Larson Dep. 188:16-21; Larson Dep. 235:1-7, 237:22-25; 236:1-9; Ex. 27, GP 00034144; Nov. 13, 2013, Larson email to Richardson (re: Dr. Feyssa, a "Viread loyalist." "Please invite this HCO to the community speaker training. At this late in the game, please offer either speaker training).

[184] Deposition of Jane Wu, March 19, 2021, . 93:18-23.

[185] OIG Guidance, at 23739-40.

must exercise independent judgment, be responsible and accountable,[186] and is bound foremost by duty to the organization.[187]

The Compliance department should establish compliance functions with the approval of senior management, legal counsel, and the Board. This responsibility should not be delegated to Sales or Marketing.[188] The Compliance department should be able to spot-check potential Speaker Program risks without advance notice or first obtaining permission from Sales.

At Gilead, the Business Conduct department did not interact effectively with Sales and Marketing on the Viread and Vemlidy Speaker Program and Ad Board issues. The Business Conduct department's effectiveness suffered from its isolation from Sales and Marketing operations, deferring to Sales and Marketing on multiple compliance issues, failure to conduct compliance risk assessment, and a lack of accountability by Sales and Marketing for compliance issues.

Findings:

- **The Gilead Business Conduct department was ineffective at controlling compliance risks with respect to Speaker Programs and Ad Boards involving Viread and Vemlidy.**
- **The Business Conduct department was not involved with the actual operation of the Speaker Programs or Ad Boards.**

[186] *Id.* at 23739.

[187] Health Care Compliance Association, "Code of Ethics for Health Care Compliance Professionals"; http://hcca-info.org/Portals/0/PDFs/Resources/HCCACodeOfEthics.pdf, § R2.4, p. 5.

[188] OIG Guidance, at 23739-40.

The Business Conduct department was not an effective presence with respect to the Viread and Vemlidy Speaker Programs and Ad Boards. It had little apparent Speaker Program or Ad Board oversight function other than approval of the general POA, the RFA for a Speaker Program or Ad Board, approval of the number of Speakers, and the presentation slides.[189] Therapeutic Specialists, AHM, or Marketing handled most of the compliance-related Speaker Program issues.[190]

With respect to its involvement in Speaker Programs and Ad Boards, Business Conduct approved the RFAs for Speaker Programs and other promotional events.[191] It approved the number of Speakers in the Speakers Bureau, although the OLP determined the appropriate number as part of the Business POA.[192] The Business Conduct department could and did approve exceptions to the FMV payments to Speakers or Ad Board participants.[193]

Despite the high risk of compliance and AKS violations, the Business Conduct department had little to do with actually overseeing the Viread or Vemlidy Speaker Programs and Ad Boards. This is another example of the compartmentalized compliance structure at Gilead. The Marketing department, and not the Business Conduct department, oversaw the Speaker

[189] Sarntinoranont Dep. 28:8-18, 30:7-17.

[190] *Id.* at 31:13-21 (Ad Boards held after every conference); 32:7-20 (minimum of three Ad Boards per year).

[191] Marketer Business Conduct Training, May 2017, GP-00132509, 00132513.

[192] *Id.* at GP 00132523, 00132520.

[193] *Id.* at GP 00132518-519.

Programs and Ad Boards. The separation of Sales and Marketing business units from Business Conduct is typical in poorly functioning compliance programs. By keeping the departments in silos, organizations are able to provide a compliance program on paper that is not adhered to in operations.

The Marketing department was responsible for physician Speaker selection and training, Ad Board selection, setting the overall budget for programs, preparing the content, preparing business POA for Speaker Programs, tracking physician Speaker and attendee prescriptions, setting the amount spent on dinners, and selecting the venues. The Marketing department ran the Ad Boards although Sales managers attended these meetings. The burden of ensuring Speaker Program and Ad Board compliance fell on TSs, managers, or outside vendors like AHM which handled Speaker Program logistics.[194] The Business Conduct department had minimal and inadequate involvement in the actual operations of the Speaker Programs and Ad Boards other than approving the meeting plan and slides.[195]

[194] AHM was only one of several vendors that helped Gilead manage the Speaker Programs or Ad Boards during the review period. Others included The Lockwood Company, P-Value, and Clinical Minds (Ad Boards). See Larsen Dep. 82:14-83:15, 84:9-15, 85:1-7; Cummings Dep. 30:4-24, 31:1-9 (AHM monitors Speaker Programs to make sure "we're in compliance" including the "correct number of customers, meal limits." Cummings as RD did not receive compliance reports from AHM.)

[195] Johnson Dep. 118:9-14 (Business Conduct purportedly reviewed the sign-in sheets for Speaker Programs, and would alert Sales managers if someone attended who was not a "standard attendee or target.") I found nothing to corroborate that Business Conduct reviewed the sign in sheets such as emails or communications alerting Sales managers to the problem.

High level compliance officer involvement in actual Speaker Program oversight was limited. Gilead apparently had an enterprise-wide North America Compliance Review Committee ("NACRC") with oversight of all "franchises." However, this committee's review of the Viread and Vemlidy Speaker Programs must have been limited. For example, the NACRC met for two hours in November 2016, and again in March 2017 for another two hours. During the March meeting, the committee heard a 60-minute presentation of Speaker Program details covering nine separate clinical or geographic areas. This limited amount of time was inadequate to cover Gilead's Speaker Program compliance risks with respect to its promotion of Viread and Vemlidy.[196]

David L. Johnson, Vice President of Sales and Marketing, testified as to his belief that Business Conduct reviewed all of the Speaker Program attendance sheets to determine whether attendees who were marked by Sales as a non-HCP or "other" in the attendance sheets were appropriate attendees.[197] I could not find any corroboration for this statement. In fact, Gilead's 30(b)(6) designee testified that there was no formal policy for monitoring or reviewing the attendance sheets.[198] Indeed, it was not even possible to determine whether someone was an appropriate attendee by looking at Gilead's speaker sign-in sheets and there was no field in the sign in sheet (or elsewhere) that required a

[196] See NACRC, March 24, 2017, GP 00332239.

[197] Johnson Dep. 129:3-25, 130:18-131:15.

[198] Chien Dep. (Day 1) 137:16-22.

TS to explain how an attendee at a Speaker Program qualified as an appropriate attendee.[199]

Compliance with Speaker Program policies was not "tested." I found no comprehensive Speaker Program or Ad Board risk assessment, no organized review to assess non-compliance with the Speaker Program policies, and no development of an annual audit plan or monitoring plan relative to Viread and Vemlidy Speaker Program or Ad Board compliance risks. I found only a few references to Business Conduct investigations conducted into alleged misconduct or non-compliance with Speaker Program or Ad Board policies.

In addition to its other deficiencies, the Business Conduct department was too small, and stretched too thin, to be effective. During the Review Period, Gilead did not have compliance-related employees dedicated solely to HBV, instead those employees were responsible for all of the approximately 7 therapeutic areas within Gilead.[200] There were no clear cut lines indicating who was responsible for the various therapeutic areas within Gilead within the litigation and investigations team.[201] The Business Conduct department, which was responsible for all therapeutic areas and not just HBV, only had approximately two people in 2013, a number which increased only nominally to

[199] Deposition of Gilead's 30(b)(6) Representative, Erica Chien, April 30, 2021 (Day 2),134:24-135:8, 135:23-136:11, 138:14-139:5.

[200] Chien Dep. (Day 2) 96:7-97:19.

[201] Chien Dep. (Day 1) 78:11-14.

approximately 10 people in 2019.[202] That inadequate staffing only included 1 business conduct attorney dedicated to HBV during the entire Review Period.[203]

Given the obvious compliance risks, the Business Conduct department's limited oversight of the Speaker Programs and Ad Boards was seriously deficient and ineffective in detecting, monitoring, or preventing compliance issues.

VIII. TRAINING AND EDUCATION

Compliance training is the third element of an effective compliance program.[204] A pharmaceutical manufacturer should communicate compliance standards through mandatory training programs.[205] Training should explain compliance requirements in a practical and concrete manner.[206] All employees, managers and contractors should receive general compliance training on applicable state and federal health care program requirements.

Employees and contractors whose jobs make certain information relevant should receive additional specialized training; for instance, sales representatives, or therapeutic specialists, should receive focused training on the AKS, and how it

[202] Chien Dep. (Day 2) 99:1-5.

[203] *Id.* at 96:1-97:19.

[204] OIG Guidance, at 23731.

[205] *Id.* at 23741.

[206] *Id.* at 23738-39 (training program for sales force should be "regular and comprehensive" including familiarizing sales force with minimum PhRMA code standards), at 23740 (encouraging companies to "explain specific requirements in a practical manner.")

applies to pharmaceutical sales and marketing practices.[207] Post-training review determines if training was effective.

Training and education are meant to prevent and remediate risk. Pharmaceutical manufacturers should identify potential training subjects through internal audits and ongoing monitoring. Training should explain the Business Conduct department's duty to monitor risky activities and enforce compliance. Pharmaceutical companies should also tell employees about management's duty to respond to compliance violations and outline the corrective actions available including disciplinary action, reporting, and repayment. Therapeutic Specialists should be tested before and after training to determine if the compliance message "sticks."

Findings:

- **Gilead's compliance training program regarding Speaker Programs and Ad Boards was ineffective because the compliance policies were not followed in practice.**

Annual compliance training at Gilead was electronic.[208] TSs were required to take two electronic business conduct courses before making product-related calls in the field. The courses (an Overview of Business Conduct, and the Annual Business Conduct Recertification) took a total of one hour and

[207] *Id.* at 23740.

[208] Johnson Dep. 70, 71:1-8, 72, 73:1-18 (Business Conduct delivered compliance training online once a year. This took about 30-45 minutes); 72:1-16 (compliance training was also conducted at annual Sales meetings once a year, and again at a mid-year Sales meeting. This took about 30 minutes); 74:1-9 (compliance training also delivered during onboarding).

40 minutes to complete. In addition, a live presentation was given by a member of the Business Conduct team during orientation.[209]

I found no evidence that the effect of the training was analyzed or that compliance knowledge was meaningfully tested before and after training to see if the compliance message "stuck." There was annual recertification training that, at some point during the Review Period, added a module dealing with Speaker Programs.[210] However, I found no evidence that the results of any compliance auditing or monitoring were used to develop a risk reduction program through training.

The Business Conduct department delivered compliance training explaining how to appropriately promote products. It also provided training on the AKS and on interactions with HCPs including Speaker Programs, Speaker Training, and Ad Boards.[211] Annual formal speaker training for the sales force consisted only of a 45-minute compliance session at the annual national meeting; a 45-minute compliance session at the mid-year meeting; and an annual business conduct recertification that could include speaker program materials.[212]

[209] See GP 00038414, Business Conduct (new hires are to adhere to the Business Conduct Manual and Code of Ethics).

[210] Chien Dep. (Day 2) 89:8-90:14.

[211] See Business Conduct Rev., HBV New Hire Training (Sicilian) (June 27, 2017), at p.15; GP 00132507.

[212] Chien Dep. (Day 2) 86:2-9, 88:3-9, 89:9-17.

Typically, the Business POA provided information regarding the number of advisors or Speakers to be used and trained each year. The Business Conduct department participated in Speaker Training for each Speaker and which consisted of 45 minutes of compliance related training a year.[213]

During compliance training, Business Conduct outlined various cases brought under the AKS. For example, in 2018, the Compliance Department provided a presentation at a national meeting and referred to other cases brought against pharmaceutical companies where Speaker Programs had been an issue due to spousal attendance, meal costs, and misrepresentation of appropriate attendees.[214]

Business Conduct advised Sales that although they were working with a vendor, Sales had a responsibility to ensure compliance with Gilead policies.[215] For instance, the Business Conduct department advised managers and Therapeutic Specialists at the 2017 national meeting that Ad Board meetings should not be used: (1) to reward or encourage the prescription or use of Gilead products; (2) to obtain information reasonably available from other sources; or

[213] Marketer Business Conduct Training, May 2017, GP 00132509-562; Chien Dep. (Day 2) 101:21-102:5.

[214] See "Cracking the Code to Compliance" (Nguyen), 2019, (raising the Actelion, Tricor and Abiomed settlements), GP 00324478, 00324488.

[215] See HBV Business Conduct Update, Mark Andrews (2015), GP 00216626, 00216650 ("As the host, you are responsible for ensuring program compliance from start to finish"…"invite appropriate HCPs to attend educational portion of the program."). This raises a question about who attended the ***non-educational portion*** of the program and ***acknowledges a social aspect*** to the meetings.

(3) to obtain duplicative feedback (including feedback obtained through other functions).[216]

The compliance training was not effective, because employees routinely ignored compliance rules about legitimate attendees and the prohibitions against using Speaker Programs and Ad Boards as relationship-building or promotional opportunities.[217]

IX. EFFECTIVE COMMUNICATION

OIG Guidance identifies communication as the fourth element of an effective compliance program. Effective communication is: 1) meaningful access to supervisors or the Compliance Officer through open-door policies, confidentiality and non-retaliation policies; and 2) the use of hotlines, e-mails, newsletters, suggestion boxes and exit interviews. Employees should be able to report matters on an anonymous basis. The Compliance Department should maintain a record of these reports and the results of any investigation conducted.[218]

Findings:

- **Gilead's communications about Speaker Programs and Ad Boards were inconsistent and confusing. Sales communications took priority over compliance.**

[216] See Business Conduct Update, 2017 National Meeting, Silician, GP 00132790, at 809.

[217] See Sections VI (A) & (F) supra.

[218] OIG Guidance, at 23741.

A. Communications to the Salesforce Contained Mixed Messages

Supervisors usually play a key role in responding to employee concerns about compliance issues. At Gilead, the managers' primary job was to promote sales.[219] I did not find examples of regular, effective compliance communication between Therapeutic Specialists and their managers, on the one hand, and the Business Conduct department about the marketing of Viread and Vemlidy, or their use of Ad Boards and Speaker Programs, on the other. Business Conduct provided compliance training but I did not find much evidence of regular, direct email, or verbal conversations with Therapeutic Specialists on specific compliance concerns.[220]

The Business Conduct department's communications to Sales and Marketing regarding Speaker Programs and Ad Boards contained inconsistent messages. For example, in 2016, the Business Conduct department warned Gilead Sales personnel to avoid developing business POAs that could be misinterpreted by regulators. BCM warned that promotional campaigns were supposed to be aimed at "on-label prescribers."[221]

At about the same time, Business Conduct advised Marketing, and Commercial Planning and Operations, to develop and submit strategic plans for the use of Advisors, Speakers, or other HCP consultants for the year (Gilead was

[219] Sarntinoranont Dep. 50:12-51:6.

[220] Cummings Dep. 34:1-7 (Regional Director Cummings never received a question about whether a receptionist was an appropriate attendee.)

[221] See GP 00132520.

planning to launch Vemlidy at this time). This analysis was supposed to include the prior year's utilization data (from 2015) and the business rationale for the number of Speakers or Ad Boards.[222] However, I could find no evidence that Business Conduct actually reviewed the business rationale for the number of Ad Boards and Speakers and it appeared that just used historical numbers.[223]

In another example of inconsistent compliance messaging, the BCMs and compliance policies required that Speakers were to be paid FMV for their services. However, exceptions were made by Sales and Marketing and Speakers sometimes received more than FMV.[224] As another example of inconsistency, Speakers were paid for the Speaker Programs even if no attendees showed up despite the rule that at least four attendees were required to be present.[225]

Business Conduct cautioned in 2016 that Ad Boards were designed to "obtain feedback, not promote." Business Conduct further stated that Marketing should not use the Ad Boards to "educate customers on the latest

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[222] See Business Conduct, Planning Principles, Process, and Documentation, (January 2016), GP 00132563-5.

[223] Business Conduct Recertification, 2016, GP 00281544, 45 ("Each year, the number of advisory meetings, and advisors must be justified in the Business Plans for Commercial and Medical for each therapeutic area." "A legitimate business purpose must be documented in the Request for Approval…" "Advisory Meetings are only necessary when we can't obtain the information we are seeking anywhere else. Advisory Meetings are not opportunities to push Gilead data, but to receive requested feedback.")

[224] Johnson Dep. 113:5-114:19 (FMV exception recommendation made by OLP leader and approved by Vice President of Sales and Marketing).

[225] Johnson Dep. 126:11-127:18; 208:18-210:25, Ex. 13, GP 00193399, Sept. 13, 2017, email from salesforce.com to Cruz (six attendees to attend, five did not show. Therapeutic Specialist's explanation sufficient to allow Speaker to be paid).

data." However, in the same presentation, Business Conduct offered guidance that the number of Ad Board meetings could be based on "new data" or the "lifecycle of the product."[226]

Business Conduct stated that Marketing should leverage OLP Ad Board engagements to gain "input and feedback" on "new and future competitors" that would impact the market.[227] Despite the language that Ad Boards were not to be used to "promote" the new product (in this case, Vemlidy), Business Conduct's communications on this issue were unclear.[228] For example, I found communications suggesting that Marketing's promotional materials should be used "immediately" around the time of the Vemlidy launch with respect to Ad Boards. This seems inconsistent with the idea that Ad Boards were designed to engage physicians with messaging about how to better communicate the risks and benefits of a particular product.[229]

Gilead's compliance communications were also undercut by the compensation methodology for the TSs. TSs were compensated on metrics that could easily incentivize non-compliance with the AKS; in effect, to succeed, TSs

[226] Business Conduct Recertification, 2016, GP 00281544.

[227] Larson Dep. 42:6-18 (Gilead allegedly does not consider market share when determining whether HCPs should be invited to sit on Ad Boards); Larson Dep. 45:1-5 ("An advisory board is a marketing tool used to provide and gain feedback from advisors or customers on important market events or market data, or data that would help shape the market.")

[228] Business Conduct Review, HBV, New Hire Training, Sicilian, (June 27, 2017), GP 00312507.

[229] HBV Post-AASLD Virtual Ad Board; Request for Approval Form (TAF); "use immediately", (2016), GP 00019089.

were driven to market Viread and Vemlidy through the use of payments to HCPs for Speaker Programs, Speaker Training, and Ad Board attendance.[230]

The methodology for the TSs' compensation was inconsistent with the compliance message that Speaker Programs were supposed to educate and inform the HCPs about the benefits and risks of Gilead products, or provide scientific and educational information, and that the Ad Boards were designed to solicit input from experts in the field.

B. Communicating Issues Upstream To Senior Management

Effective compliance communication also involves communicating upstream to senior management. Speaker Programs were a key part of the Viread and Vemlidy marketing plans.

The number of Speaker Programs that a TS hosted was part of his or her performance evaluation.[231] TSs were expected to have two to three targets in attendance at each Speaker Program.[232] The pressure to perform and Gilead's compensation methodology appears to be one reason that TSs and others did not take their compliance concerns to senior executives.

The Sales and Marketing managers also did not appear to communicate compliance concerns to their peers. For example, the Commercial Operations

[230] Chan Dep. 58:22-59:6 (her compensation and bonuses were based on the prescription writing habits of HCP in her territory).

[231] See Koomey email to Groome, re: "Spend, spend, spend," October 23, 2013 (transferring $35,000 to G event account, and encouraging team to "input programs asap."); Sarntinoranont Dep. 77:13-25, 78:7-17.

[232] Johnson Dep. 202:18-25, 203:2-22, Ex. 12, GP 00122802, Aug. 5, 2015, email from Johnson to Spivock.

group tracked the number of programs budgeted, sales effectiveness, Speaker Program execution, and numbers. Commercial Operations published a dashboard that Sales and Marketing could use for data analysis. This information was purportedly used to make sure that the TSs were using Speakers appropriately and meeting internal metrics.[233]

Sales and Marketing received similar information about the Ad Boards. However, it did not appear that this data was used in conjunction with any review of Speaker Program or Ad Board compliance. The lack of communication between Sales and Marketing and Business Conduct is remarkable because of the Speaker Program attendance issues, the risks involved, and Polaris's assessment that the Speaker Programs often had a social element.

X. AUDITING AND MONITORING

Internal auditing and monitoring are the fifth element of, and the keystones to, an effective compliance program.[234] The Compliance department should set up a system to measure whether the organization is meeting measurable benchmarks or goals, and if goals are not being met, determine why, and plan to improve compliance.[235] The scope and frequency

[233] Johnson Dep. 101:1-13, 102:1-20, 103:1-9, 104.

[234] OIG Guidance, at 23731, 23741.

[235] See OIG: Health Care Fraud Prevention and Enforcement Team, Provider Compliance Training slides; https://oig.hhs.gov/compliance/provider-compliance-training/files/Provider-Compliance-Training-Presentationv2.pdf; Operating an Effective Compliance Program; https://oig.hhs.gov/compliance/provider-compliance-training/files/OperatinganEffectiveComplianceProgramFinalBR508.pdf.

of compliance review (auditing or monitoring) depends on the company's size, available resources, prior history of non-compliance, and identification of risk factors.[236]

Evaluators with relevant expertise should perform regular compliance reviews and focus on departments that are involved in billing federal health care programs (such as Sales and Marketing). Audits should determine if there are controls in place to adequately manage risks. Specifically, they should evaluate whether: (1) the pharmaceutical manufacturer has adequate policies to mitigate exposure in identified risk areas; (2) the policies were implemented and communicated; and (3) the policies were followed.[237]

Gilead did not effectively conduct these kinds of compliance audits or reviews of the Viread and Vemlidy Speaker Programs and Ad Boards. The Polaris compliance reviews were apparently not used to identify and effectively address the compliance risks in the Viread and Vemlidy Speaker Programs or Ad Boards.

Finding:

- **Gilead did not perform effective auditing and monitoring of the Viread and Vemlidy Speaker Programs and Ad Boards despite knowing these events presented high compliance risks.**
- **Gilead had ample information available to conduct a risk assessment of the Speaker Programs and Ad Boards. It failed to do so.**

[236] OIG Guidance, at 23741.

[237] *Id.*

- **Gilead tracked the prescriptions written by both Speakers and attendees. It tracked payments to the Speakers and Ad Board participants. This information or data was not used to reduce the risk of noncompliance.**

Gilead's failure to implement an organized auditing and monitoring plan with respect to the Viread and Vemlidy Speaker Programs and Ad Boards was one of the main reasons for the compliance program's lack of effectiveness. Although Gilead engaged Polaris to monitor some of its Speaker Programs, the monitoring was minimal[238] and it did not use the Polaris monitoring results in a way that reduced Gilead's compliance risks.

Sales and Marketing executives were aware of the compliance risks in paying Speakers and Ad Board physicians based on their prescribing volume and the value of those prescriptions.[239] Gilead engaged Polaris to review live Speaker Programs because of compliance concerns.[240] However, I found little evidence that Gilead used the Polaris monitoring, conducted a systematic or effective AKS compliance risk assessment of the Viread and Vemlidy Speaker Programs or Ad Boards, or used the vast array of other data it collected during the Review Period to manage, or reduce those risks. I conclude that this was a major factor in the compliance program's lack of effectiveness.

[238] Chien Dep. (Day 1) 112:11-22 (Polaris only monitored approximately 7 Speaker Programs per year.)

[239] See for example, HBV Business Conduct Update, Mark Andrews (2015), GP 00216626, 00216649.

[240] See Sarntinoranont Dep. 336:5-13.

A. The Business Conduct Department Failed to Conduct a Compliance Risk Assessment of the Viread and Vemlidy Speaker Programs and Ad Boards

An effective Compliance department, or its designee, identifies risks through a compliance risk assessment.[241] The risks are typically quantified; this can be done by a probe sample (non-statistically significant) followed by data analysis to determine the extent of the risk, its probability and magnitude of potential damages. If a probe sample shows a high error rate (over 5%), the Compliance department must investigate further.

I found no evidence of this kind of organized risk analysis being conducted to assess the Viread and Vemlidy Speaker Programs or Ad Boards to determine if the compliance policies were being followed, to test the number of times the same HCPs attended repetitive Speaker Programs, to determine how many times exceptions were being granted by Sales or Marketing for fair market value or meal limits, to determine if Speakers were attending Speaker Programs as attendees, or how many times a Sales representative invited inappropriate, non-prescriber, non-HCP attendees to a program.

Setting up a program of annual auditing and monitoring is standard in the health care industry. Auditing and review techniques are set forth in the OIG's

[241] See, U.S. Department of Justice, Evaluation of Corporate Compliance Programs, April 2019 (when evaluating a corporate compliance program, prosecutors should consider "[t]he effectiveness of the company's risk assessment and the manner in which the company's compliance program has been tailored based on that risk assessment" and whether its criteria are "periodically updated." See, e.g., JM 9-47-120(2)(c); U.S.S.G. § 8B2.1(c) ("the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement [of the compliance program] to reduce the risk of criminal conduct"); https://www.justice.gov/criminal-fraud/page/file/937501/download.

Self-Disclosure Protocol and in CIAs published on the OIG's website.[242] Gilead's Business Conduct department should have conducted a compliance risk assessment of the Viread and Vemlidy Speaker Programs followed by an annual audit plan. It should have monitored the TSs and managers whose Speaker Programs were noncompliant.

Notably, Gilead did not have a formal internal monitoring process regarding its Speaker Programs.[243] Gilead's Internal Audit department did conduct an audit of the U.S. Speaker Program process in 2014. However, I was not provided with a copy of this audit. The internal audit was designed to document selection processes, review utilization of speakers and attendance, and review whether compensation was consistent with fair market value.[244] Review of Speaker utilization and Speaker Program attendance should have provided the Business Conduct department with sufficient information to assess the compliance risks and gaps in the program. However, I found no information to indicate that Business Conduct used the Internal Audit results to enhance the compliance program.

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[242] See OIG: Office of Audit Services, "RAT-STATS 2010 User Guide," Version 1, at http://oig.hhs.gov/organization/oas/ratstats/UserGuide2010_04js.pdf; and OIG: "An Open Letter to Health Care Providers," Nov. 20, 2001; https://oig.hhs.gov/fraud/docs/openletters/openletter111901.htm (noting that a full statistically valid random sample will be required where the initial claims review identifies an "unacceptably high error rate," defined as over 5%, as set forth in the "Summary of New CIA Claims Review Procedures:" https://oig.hhs.gov/fraud/docs/openletters/openlettersumm111901.pdf).

[243] Chien Dep. (Day 2) 93:1-16.

[244] See email from Navarro to Bushnell, July 31, 2014, GP 00186164.

Gilead also engaged Polaris to conduct on-site monitoring of Speaker Programs. Gilead produced a SP Monitoring Summary from the Polaris information.[245] From 2013 through 2019, approximately 52 Viread/Vemlidy programs were reviewed by Polaris. From 2013 through mid-2015, these monitoring events were announced.[246] By mid-2015, Polaris changed its monitoring to unannounced monitoring. I did not find anything in the record to indicate why the type of monitoring was changed though unannounced monitoring is generally more reliable in providing a true snapshot of business practices. Apparently, some announced monitoring continued as well.[247]

Another notable change in the Polaris monitoring was that the amount of monitoring increased from about 4-5 events to 15 monitored events in 2019. Again, I did not find evidence that this monitoring was used to enhance the compliance program despite the increase in the number of monitored events and the change from announced to unannounced monitoring.

Polaris monitored the appropriateness of the attendees (purportedly to ensure that only HCPs likely to prescribe Gilead products were in attendance), attendance thresholds (minimum number (4) of appropriate attendees), the sign-in sheets (relevant information captured), venue (appropriate and

[245] See Speaker Program Monitoring Summary, GP 0006201; and see Speaker Program Monitoring FAQs, 2013 GP 00200935.

[246] See, for example, email from Larson to Wolfgang, June 19, 2014, GP 00208757, and see GP 00208755.

[247] See GP 00214837-38 (Polaris monitors contacted each TS/IS to coordinate logistics before the scheduled program).

conducive to scientific discussion), and meal limits (compliance with policy).[248] Business Conduct did not use this information to enhance its compliance program or prevent noncompliance.

In fact, it was Gilead's policy not to provide the third-party Polaris monitoring reports to the TSs who were responsible for the Speaker Programs being monitored and there was no policy requiring business conduct to have a discussion with a TS who had hosted a monitored Speaker Program even if the monitoring report indicated potential non-compliant conduct.[249] Further, there was no policy requiring subsequent monitoring of Speakers after a Polaris report revealed compliance-related issues, no formal policy in place for monitoring or reviewing the Speaker Program sign-in sheets and no formal policy in place for monitoring the appropriateness of attendees at Speaker Programs.[250]

B. Gilead Failed to Audit Event Data for Compliance

Gilead and its Speaker Program vendor, AHM, produced materials to Plaintiffs' counsel as part of discovery. I was provided with copies of these documents and summaries of voluminous material in various spreadsheets. I reviewed the spreadsheets prepared using material provided by AHM.[251]

AHM provided substantial data that Business Conduct could have used to identify and address compliance risks. The information from AHM recorded

[248] 2017 Speaker Program Monitoring, GP 00214834, 00214838.

[249] Chien Dep. (Day 1) 117:12-14, 121:9-16.

[250] Chien Dep. (Day 1) 126:10-17, 137:16-22, 142; 20-143:3.

[251] AHM 000001.

Speakers by their first and last names, the date and location of the event, the sales representative involved, the honoraria paid to the Speakers, and the total costs. The AHM information apparently recorded the attendees who were invited and whether they actually attended.

I reviewed "franchise reports" in an Excel format produced by AHM. Those reports tracked the events, Speakers, topics, spend, host sales representative, close-outs, and other information. The reports were used by the Sales and Marketing departments (for example, to track planned events), but I found no suggestion that these were used for monitoring purposes or improving compliance with Speaker Program policies. Gilead did not have a formal process in place for auditing the AHM data during the Review Period.[252]

Through AHM and the Polaris reviews of live Speaker Programs, Gilead knew that:

- A short period of time was being spent on actual education, medical, and scientific information during the Speaker Program dinners.
- Polaris considered some of the dinners to be social in nature.
- The attendees often included individuals who were not appropriate attendees as defined by Gilead's own policies (and as noted by Polaris).
- A number of the attendees had the same last names, worked or resided in the same building as other attendees or the Speakers.

[252] See Franchise Reports (GP 00272447, 449 and GP 00272455 (2017)); Chien Dep. (Day 2) 47:9-14.

- A number of attendees were not likely prescribers of HBV drugs (billing staff, receptionist, student nurse, gynecologist, dermatologist) as required by Gilead's policies.

- Speaker Program dinners were held at high-end restaurants where meals and alcohol were served.

- Many attendees were repeat attendees despite little change in the slides or presentation. The repeat attendee problem apparently continued into 2018 as documented by the Business Conduct department's training.

With respect to the Ad Boards, Gilead collected information from a variety of vendors, including the Lockwood Company, Clinical Minds, and P-Value.[253] From this information and data, Gilead knew that:

- The Ad Boards were supposed to seek input needed in relation to a legitimate business purpose. The Ad Boards were not supposed to be promotional or educational events. However, the prescriptions written by Ad Board participants and others were tracked. [254]

- The Ad Board participants were supposed to be selected based on their expertise. However, Sales recommended participants for the Ad Boards. Sales and Marketing reviewed potential Ad Board member prescriptions when making a selection about whom to invite.[255]

- Sales personnel and therapeutic specialists (TSs) attended Ad Boards in a "silent observer" status. TSs purportedly did not talk to the Ad Board participants although they went to the Ad Board

[253] AHM helped Gilead manage Speaker Programs and had some involvement with Ad Boards. Companies that appeared to help Gilead stage and manage Ad Boards included Lockwood, Clinical Minds, and P-Value (see Larson Dep. 82:14-25, 83:1-15; 84:9-25, 85:1-7).

[254] See Larson Dep. Ex. 12, and Larson Dep. 167:14-168:25 (Gilead tracked Ad Board participant prescriptions).

[255] *Id*. see Larson Dep. Ex. 4, Tang email to Groome, March 17, 2015 (ACT Program Targets and market share); Larson Dep. 140:18-25; Sarntinoranont, 72:15-21, 73:6-18, 74:9-17, 75:1-19.

dinners. The TSs considered Ad Boards as another Gilead mechanism to boost sales.[256]

- Ad Boards were held at attractive venues. Attendees were asked about subjects that were marketing in nature; for instance, information about Gilead's competition.[257]

Any of these areas should have caused Gilead to review its physician marketing efforts for Viread and Vemlidy for AKS and compliance risks. Nevertheless, Gilead did not regularly monitor Ad Boards and, to the extent it did, it was "not a high number," maybe once per year.[258]

Through AHM, Gilead was capable of capturing every attendee at the Viread and Vemlidy Speaker Programs.[259] One-on-one meetings are not truly Speaker Programs if the only participants are the Speaker and the Gilead sales or marketing representatives.[260] Paying Speakers for events with no attendees undercuts the argument that Speakers were being paid to provide scientific or educational information about the drugs. If no one attended, the Speakers performed no services but were paid anyway.

[256] See Larson Dep. Ex. 6, Groome email to Larson, September 29, 2017 ("I know [Marissa] is going to be so grateful for you having an Ad Board in Seattle to help her increase her Vemlidy sales.")

[257] Business Conduct Planning Principles, Process, and Documentation (January 2016), GP 00132563, 65.

[258] Chien Dep. (Day 2) 125:22-126:7.

[259] Johnson Dep. 126:1-10 ("we knew who showed up.")

[260] Larson Dep. 253:14-254:1.

Attendee types were recorded. Although guests were prohibited by the Gilead Speaker Program policies, records revealed that the attendees were frequently office staff and "others" who were non-prescribers.[261]

Speakers were recorded as being attendees of other Speaker's events.[262] The fact that Speakers were attendees at other Speaker's Programs indicates that the events were designed to offer a benefit to the Speakers and their fellow attendees; including the opportunity to socialize and enjoy an expensive meal. It also undercuts the argument that the purpose of the Speaker Programs was to educate the attendees.

The attendee data also shows that certain attendees were frequent attendees at the dinners. Repeat attendance reduces the appearance that the Speakers were performing a legitimate service. Sales and Marketing recognized this and tried to narrow the number of times an attendee could attend a Speaker Program. However, like other compliance rules at Gilead, this was flexible.[263]

Gilead Sales managers (and Marketing managers) sometimes attended Speaker Programs. They also went on "ride-alongs" or field visits.[264] However, I

[261] Johnson Dep. 129:1-24 ("others" would be a red flag).

[262] Johnson Dep. 118:24-25, 119:1-17, 120 ("speakers like to watch other speakers"…"that would make sense to not- to not let a speaker that already knows the- that's already been educated on a topic to continue to attend that.")

[263] Johnson Dep. 121:3-21 (attendees could go to four or five Speaker Programs, then number reduced to three); 121:17-21 ("life cycle matters.")

[264] Johnson Dep. 141:1-23 142:1-10 (attended two or three Speaker Programs per year); Ex. 5, GP 0069991-992, HBV Division Field Ride Schedule, June 2015, Dep. 162:18-163:6.

did not find much evidence to indicate that the field visits by managers were concerned with compliance instead of sales. In fact, the field visit schedule form that TSs were required to use included the names of the doctors to be visited, how high a decile prescriber the doctor was, the doctor's market share for prescriptions of Gilead drugs and whether the doctor was a Speaker but did not include any information about compliance.[265] This was not "monitoring" as OIG has described in its Guidance. There appeared to be no effort to fold the results of the field visits into the compliance program.

There was simply no organized compliance monitoring or auditing of the Viread and Vemlidy Speaker Programs or Ad Boards. This was a substantial and unaddressed compliance gap.

XI. INVESTIGATIONS AND DISCIPLINE

The sixth element of an effective compliance program is the enforcement of standards through well-publicized disciplinary guidelines. The Compliance Officer is responsible for "[i]independently investigating and acting on matters related to compliance." The Compliance Officer responds to reports of problems or suspected violations and should be able to take appropriate disciplinary actions.[266] Internal investigations should lead to immediate remediation. Investigations should be conducted whenever the Compliance Officer has a "reasonable suspicion" to believe there is a violation of policies,

[265] Chan Dep. Ex. 2 GP 00038244, 64:18-65:20, 66:12-67:5.

[266] OIG Guidance, at 23740.

law or regulations.[267] Despite the Company's wide-spread practices over several years, I found only a few instances of the Business Conduct department or its designee vigorously investigating compliance violations.

The compliance program should include specific disciplinary policies explaining consequences for violating the law or written compliance standards.[268] Intentional non-compliance should reliably subject transgressors to sanctions ranging from verbal warnings to additional training, compensation claw backs, suspension, termination or other measures. For discipline to have a deterrent effect, a pharmaceutical manufacturer must undertake consistent disciplinary action across the company.[269]

Findings:

- **Gilead did not conduct systematic or effective investigations of compliance violations involving the Viread or Vemlidy Speaker Programs and Ad Boards.**

A. Minimal Investigations of Compliance Violations

I found very few instances of investigations of compliance violations or remedial actions by Gilead.[270] To the contrary, the culture at Gilead did not foster reporting of noncompliance.

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[267] *Id.* at 23742.

[268] OIG Guidance, at 23741-2.

[269] See 2011 U.S. Sentencing Guidelines Manual, p. 515, Commentary to § 8B2.1. Effective Compliance and Ethics Program; https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2011/manual-pdf/2011_Guidelines_Manual_Full.pdf; ("Recurrence of similar misconduct creates doubt regarding whether the organization took reasonable steps to meet the requirements of this guideline.").

[270] Cummings Dep. 46:12-25, 47:1-7 (Graham Warden had a non-compliant Speaker Program. She was education and matter reported to Business Conduct.)

For instance, I found emails about an individual (Samuel Lee) who, in 2015, expressed concerns about compliance and the business conduct of his sales partner at that time, Catherine Chan.[271] Mr. Lee set forth specific and serious allegations regarding the business conduct of Ms. Chan. Among his allegations, Mr. Lee alleged that during his first Speaker Program event with Ms. Chan in July 2013, the dinner was held in the main dining room of a restaurant, rather than in a private room, and that there were no program books used and no formal discussion of HBV.[272] Records related to the event confirm that the date of the program identified by Mr. Lee, as well as the Speaker he identified, were accurate.[273]

Mr. Lee identified two events in September 2013 at which no actual program was presented.[274] Again, contemporaneous records confirm that the dates and "Speakers" identified by Mr. Lee were accurate.[275] Mr. Lee also described an event in November 2013 at which close to 20 inappropriate attendees were present, no slide presentation was given and there was no

[271] See Johnson email to Schmalzle, Feb. 5, 2015, (Re: Violations of Gilead Business Conduct Policy – HBV Flushing Territory), GP 00210705; Larson Dep. 68:5-19, 86:17-25 (Ms. Chan is now part of Hepatitis B marketing and works directly for Ms. Larson managing Gilead Speaker Programs).

[272] GP 00210705.

[273] Chan Dep. Ex. 5.

[274] GP 00210705.

[275] Chan Dep. Exs. 6, 7.

formal discussion of HBV.[276] Once again, records confirm the verifiable portions of Mr. Lee's allegations.[277]

Mr. Lee further alleged that Ms. Chan concealed Speaker Programs from him, despite the fact that they were sales partners, including all events for three speakers in 2014 and an event in 2015 at which no presentation was given. Mr. Lee believed that Ms. Chan was hiding the programs from him because they were non-complaint.[278]

Gilead's Corporate Counsel responded to Mr. Lee stating that Gilead had conducted a careful and thorough investigation, but I found no information about the resolution of this matter. Mr. Lee apparently left Gilead and was not informed of the results of his complaint.[279] Ms. Chan's testimony reflects only a superficial investigation into the violations reported by Mr. Lee. According to Ms. Chan, she was interviewed by Gilead but she was not aware of anyone else (including the other Gilead employees or doctors involved) being interviewed and she did not believe that anyone else at Gilead was even aware of the alleged violations.[280] In fact, Ms. Chan testified that rather than be reprimanded or coached for these violations, she was given multiple sales-based awards in

[276] GP 00210705.

[277] Chan Dep. Ex. 8.

[278] GP 00210705.

[279] See Golis letter to Lee, April 7, 2015, GP 00134576.

[280] When Ms. Chan was promoted, her supervisor, Lelani Larson, was not even aware of the allegations against her or the resulting investigation. Larson Dep. 68:5-19; 233:15-234:2. Chan Dep. 89:19-91:25, 155:17-156:14.

2015, 2016, and 2017, and was promoted to the role of Senior Product Manager for HBV in 2018.[281]

I found another instance of a sales representative's failure to "report all reportable health care providers" and failing to ensure the accuracy of sign-in sheets. This resulted in a 2014 warning letter to the TS, Bo Kwok.[282] However, because Ms. Kwok was a highly successful TS, Gilead was flexible in its compliance enforcement. Two years after the original warning letter, in 2015, Ms. Kwok had meal overages. This violation, at least her second, did not cause Ms. Kwok to lose her status as a member of the prestigious "President's Club" in 2015 and Gilead's management was encouraged to "ensure she is in compliance and out of harm's way."[283] It wasn't until Ms. Kwok demonstrated a pattern of misbehavior over a long period of time, including driving a company car without a license, that she was terminated by Gilead.[284]

Rather than enforcing its standards through well-publicized disciplinary guidelines, Gilead's investigations and disciplinary policies were shrouded in secrecy. Other than the basic concepts set forth in the BCMs, Gilead did not make its written Internal Investigations and Disciplinary Policy available to employees until November 2018. Prior to November 2018, the Internal

[281] Chan Dep. 40:7–41:14, 61:19-63:11.

[282] See Zlatar letter to Kwok, April 4, 2014, GP 00277810.

[283] See Pemberton letter to Schmalzle, Feb. 11, 2016, GP 00108282, see also GP 00108284.

[284] Johnson Dep. 174, 175:1-1-17 ("it was just a pattern of behavior over time of these type of violations that caused it to be a more urgent issue"…"a period of time not having a driver's license when she had a company car.")

Investigations and Disciplinary Policy was not on "paper."[285] There was no written threshold about when Gilead would undertake a compliance investigation; it was just a "judgment call."[286]

The failure to enforce standards through well-publicized disciplinary guidelines is contrary to the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers.[287] Failing to communicate the consequences of compliance violations and instead cloaking them in privilege are hallmarks of an ineffective compliance program.

In many respects, any Gilead TSs who were concerned about Speaker Program compliance enforcement, such as Sam Lee, were flying blind. During the Review Period, there was no written policy that explained to employees when a compliance issue would be elevated to an investigation.[288] Sales managers were not given specific direction about when they had to elevate a compliance issue that had been reported to them. There was no written disciplinary policy or investigations policy regarding how to deal with potential compliance violations by third parties acting on Gilead's behalf such as HCP Speakers.[289]

[285] Chien Dep. (Day 1) 54:3-22, 55:10-12, 57:7-15.

[286] *Id.* 62:3-8, 63:8-16.

[287] May 5, 2003, OIG Guidance, 23731.

[288] *Id.* 66:24-67:4.

[289] *Id.* 70:6-16, 79:20-80:22.

During the Review Period, Gilead apparently had no written policy governing the investigation of compliance concerns arising from the conduct of a Speaker. There was no written policy governing the investigation of compliance concerns arising from the conduct of an Ad Board participant.[290] The lack of any written policies is reflected in Gilead's failure to follow up with the Speakers regarding compliance related concerns. For example, even though a Polaris monitoring report from a Speaker Program conducted by Dr. Calvin Pan at the exclusive Philadelphia restaurant Morimoto indicated that he had skipped ten slides (many of them substantive) in violation of Gilead's policy (and FDA rules), Gilead never spoke to Dr. Pan about the clear violation of its policies.[291] Similarly, even though Gilead's management received a report that Dr. Pan had failed to present any material at a scheduled Speaker Program (Roundtable), Gilead never spoke with Dr. Pan to determine if this flagrant violation of its policies had occurred or to even get his view regarding the allegation.[292]

Equally troubling, Gilead had no formal process in place that detailed how, when a compliance issue was determined to exist, to use that information throughout the company to take corrective action by training others regarding the issue. Similarly, there was no formal process in place that controlled how

[290] *Id.* 83:5-18, 83:19-84:18.

[291] Pan Dep. 153:8-12; IQV-Gilead 000051 Pan. Ex. 2.

[292] Pan Dep. 170:22-25 – 171:1-10. GP 00210705, Pan Ex. 4.

information contained in an investigation's close-out report was to be provided to the managers of an employee who was found to have acted in a non-compliant manner.[293]

Gilead appears to have tailored its discipline for compliance violations to meet the needs of Sales and Marketing, as opposed to the discipline being uniformly applied.[294] For example, at a national meeting in 2019, "proportional discipline" was discussed during a compliance presentation about the new internal investigation and discipline policy. Attendees were advised that the Gilead takes compliance "seriously" but that the "cover-up is worse than the crime." The speaker explained, for example, that the attendees should not alter receipts to hide going over the meal limits.[295] As confirmed by Ms. Chan, Gilead also fostered a culture of being careful about what was put in writing.[296] Business Conduct presentations encouraged employees to consider "[w]hat happens if this information is made public,"[297] encouraged employees to not "put in an email or text, what you wouldn't want to see printed in the newspaper,"[298] and to remember that "all e-mails are potentially

[293] Chien Dep. (Day 1) 102:16-23; 104:14-21; 100 :16-25; 101:1-17.

[294] For instance, with respect to choosing an appropriate venue for speaker programs, TSs were expected to use their judgment. Chein Dep. (Day 2) 24:22-25:10.

[295] See Cracking the Code to Compliance, Nguyen, National Sales Meeting, 2019, GP 00324478, GP 00324486.

[296] Chan Dep. 170:13-18.

[297] GP 00132565 at 575.

[298] *Id*. at 00132576.

discoverable."[299] The impact of this culture and its messages is clear – do what you need to do to drive sales, but be careful about how you do it.

The lack of investigation of compliance breaches involving the Viread and Vemlidy Speaker Programs and Ad Boards likely stemmed from the fact that TSs were responsible for reporting the compliance breaches and at least for the Speakers, making the determination if a report (verbal or not) warranted further investigation.[300] This was an ineffective compliance control because the TSs were also incentivized to keep the Speakers happy.

B. Internal Investigations Policy not Followed

Pursuant to Gilead's written policies, employees were required to promptly report any noncompliance to the manager, compliance officer, human resources, Ethics Hotline, or Board.[301] Employees were promised non-retaliation and that remedial action would be taken after investigation. Discipline ranged from a coaching to termination. I did not find much evidence, however, that this policy was followed and, in fact, as discussed above, Gilead's responses to Mr. Lee's allegations sent a far different message to Gilead's employees.

XII. RESPONDING TO DETECTED PROBLEMS AND TAKING CORRECTIVE ACTIONS

The final element of an effective compliance program is the Compliance Department's ability to immediately act upon receipt of "reasonable indications

[299] *Id*. at 00132577.

[300] See HBV Business Conduct Update, Andrews, (2015), GP 00216626; and New Tool Pre-Program Compliance Reminders; GP 00216655.

[301] Gilead Internal Investigations and Disciplinary Policy, (2018), GP 00277969, 00277971-972.

of suspected noncompliance."[302] The response following an investigation should include a corrective action plan addressing the root cause of the problem, a report and repayment to the government if necessary, and/or a referral to criminal or civil law enforcement authorities.[303] The amount of a monetary loss to a federal health care program is not determinative of whether conduct should be reported. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are necessary to protect the integrity of health care benefits programs.[304]

When a Compliance Officer discovers credible evidence of misconduct, and after a reasonable inquiry, believes it may violate criminal, civil or administrative laws, the company *must* report the misconduct to appropriate federal or state authorities within a reasonable period but not more than 60 days after determining there is credible evidence of a violation.[305] Prompt voluntary reporting demonstrates good faith and a willingness to correct the problem. Reporting the problem is considered by the OIG in determining whether to impose administrative sanctions (*e.g.*, penalties, assessments or exclusion) and by the courts in imposing penalties.[306]

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[302] OIG Guidance, at 23742.

[303] *Id.*

[304] *Id.* at 23743.

[305] *Id.* at 23742.

[306] *Id.* at 23732.

Findings:

- **Gilead did not consistently investigate, correct or report violations of the compliance policies or potential violations of the AKS.**

I found little evidence that Gilead Business Conduct had an organized approach to compliance breaches involving the Viread and Vemlidy Speaker Programs and Ad Boards. I expected to find a compliance review after Gilead learned that Speakers attended each other's dinner programs, that spouses were invited to the Speaker Programs, that Ad Boards were used to encourage prescriptions by participants, and the failure to abide by other compliance policies.

I anticipated the implementation of corrective action plans, testing, and education. At Gilead, discipline appeared to consist mainly of general education and counseling but there was no corrective action, no follow-up, little compliance reporting,[307] and no effort to continuously improve Speaker Program and Ad Board compliance during the review period. In fact, there was no formal process in place that detailed how, when a compliance issue was determined to exist, to use that information throughout Gilead to train or educate others regarding the issue.[308] Likewise, there was no formal process in place that controlled how information contained in an investigation's close-out report was to be provided to managers or superiors of an employee who was

[307] There was not even a formal process in place that detailed who within Gilead a compliance investigation close-out report should be shared with. Chien Dep. (Day 1) 100:9-13.

[308] Chien Dep. (Day 1) 100:16-101:17.

found to have acted in a non-compliant manner.[309] In sum, Gilead's approach to violations reflected, at best, a lax attitude toward compliance.

CONCLUSION

My opinion is that Gilead's compliance program with respect to the Viread and Vemlidy Speaker Programs and Ad Boards was ineffective to identify and control compliance risks including the risk of violating the AKS. Gilead did not conduct the Viread and Vemlidy Speaker Programs or Ad Boards in accordance with FDA rules, OIG Guidance, PhRMA Code, industry standards or their own internal policies. The Business Conduct department had very little involvement with the Speaker Programs or Ad Boards, and its oversight was seriously deficient. In sum, as detailed and expanded on more fully herein, Gilead's compliance with the Viread and Vemlidy Speaker Programs and Ad Boards was ineffective in that it, *inter alia*, (1) had an undersized and understaffed compliance department; (2) did not attempt to enforce its own policies contained in its BCMs as to who were appropriate attendees at Speaker Programs; (3) allowed TSs to use their own discretion to determine the "business need" for individual Speaker Programs in their territories – even though it would purportedly not permit them to nominate speakers because of sales considerations; (4) did not sufficiently train sales staff about how to conduct compliant Speaker Programs; (5) did not sufficiently train speakers how to

[309] *Id.* 102:16-23, 105:14-21.

conduct compliant Speaker Programs; (6) did not have formal policies in place for monitoring and auditing Speaker Programs and Ad Boards; (7) did not have any formal policies in place for disseminating results and compliance issues to its employees emanating from the nominal monitoring and auditing it did conduct; (8) had no meaningful oversight of the meal and beverage limitations and poor justification for its nationwide use of the $125 meal spend limit; (9) did not have well-publicized investigation and disciplinary guidelines (finally publishing one late in the covered period); (10) had no written policies detailing when a compliance investigation would be conducted; (11) had no written policies about when an employee to whom a compliance concern was presented was required to elevate that compliance concern to management or Business Conduct; (12) had no written policies governing the investigation of compliance issues that implicated non-employee Speakers and advisors; and (13) it took into account prescription writing habits and decile levels of HCPs in determining who would become Speakers and participate in Ad Boards.

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Virginia B. Evans

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May 3, 2021

Appendix A

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EXPERIENCE

Thomson Reuters, Practical Law **March 2019 - Present**
Senior Legal Editor, Health Care & Life Sciences

- Wrote, peer reviewed, and edited online health care and life sciences journal on Anti-Kickback Statute, Stark Law, False Claims Act, exclusion, self-disclosure protocols, compliance risk assessment, compliance policies, state fraud and abuse laws, long term care, telehealth, and Covid-19 resources

Virginia B. Evans, LLC, Charlottesville, VA **2016 – Present**
The Law Firm of Virginia B. Evans, PLC **2017 - Present**
Owner, Managing Partner

- Consulting and legal services for health care clients regarding a broad range of regulatory and legislative issues, including compliance under the Affordable Care Act (ACA), Stark Law and Anti-Kickback Statute
- Practice focuses on fraud and abuse issues including development and implementation of corporate compliance programs, internal reviews and investigations, and federal and state investigations arising from False Claims Act, Stark Law and Anti-Kickback Statute actions
- Analysis of potential HIPAA breaches and privacy law violations
- Clients include private healthcare entities and governmental agencies

Centra Health, Inc., Lynchburg, VA **2012 – 2015**
Vice President, General Counsel & Corporate Compliance Officer

- Created Legal & Compliance Department for a $750 million hospital system with four hospitals, post-acute care, skilled nursing facilities, surgical centers, a large physician practice, two insurance companies, and specialized schools
- Counsel to Board of Directors and management on legal, regulatory and compliance issues
- Provided legal guidance on regulatory matters during hospital acquisition of an insurance company including review of provider agreements and potential anti-trust issues.
- Provided expert guidance to Board Audit & Compliance Committee, Finance Committee, and Executive & Physician Compensation Committee
- Provided legal advice for reorganization of Board of Directors, drafted Code of Conduct and Compliance Plan and standardized Physician Recruitment and Physician Employment Contract templates for regulatory consistency
- Provided legal guidance on commercial and patient privacy issues during formation of Clinically Integrated Network (CIN), acquisition of a hospital, and several practices

Ober, Kaler, Grimes and Shriver, Washington, DC **2010 – 2012**

Shareholder/Partner, Health Care Practice

- Practice focused on government regulatory and white-collar defense, legal and compliance guidance to health care providers and pharmaceutical companies, internal investigations, voluntary disclosures, grand jury practice, and response to allegations of misconduct
- Conducted criminal, civil and administrative defense and litigation, including under state and federal False Claims Act, Stark Law, and Anti-Kickback Statute

Daylight Forensic & Advisory LLC, Washington, DC **2007 – 2010**
Managing Director, Health Care Practice

- Managed health care forensic practice and academic medical center initiatives
- Trained international clients on Foreign Corrupt Practices Act (FCPA)
- Designed audits and investigations of organizations including large hospital systems, government agencies, and national retail pharmacy chain

KPMG, LLP, Washington, DC **2005 – 2007**
Director, Forensic Services, Mid-Atlantic Health Care Channel Leader

- Conducted fraud investigations, Independent Review Organization (IRO) engagements and compliance/fraud risk assessments for health care systems, hospitals, pharmaceutical, and durable medical equipment companies
- Investigated allegations of misconduct during the audit process (Shadow Audits), provided training on FCPA, SOX 404, and regulatory compliance

United States Attorney's Office, District of Maryland **1991 – 2005**
Chief, Civil Division (2004-2005); Deputy Chief, Civil Division (2003-2004); Civil Health Care Fraud Coordinator (2001-2005); Public Affairs Officer (2001- 2003); Insurance Fraud Coordinator (1992 – 2001); Criminal Health Care Fraud Coordinator (1993 – 1997)

- As Civil Chief, supervised all civil investigations, litigation and settlements for United States including False Claims Act and Stark Law cases, managed budget and priorities
- Conducted civil and criminal trials and litigation in District Court and in Fourth and Second Circuit Courts of Appeals
- Engaged in civil defensive litigation including employment discrimination, medical malpractice, FOIA and Privacy Act, and Federal Tort Claims Act cases
- Investigated and prosecuted complex crimes, including in health care, financial institution and defense contracting fraud, computer crimes, racketeering, drug diversion, and extortion

United States Attorney's Office, Eastern District of New York **1987 – 1991**
Assistant United States Attorney

- Investigated and prosecuted criminal matters involving financial institution fraud, securities fraud, insurance fraud, income tax fraud, narcotics importation and distribution, and money laundering

United States Department of Justice, New Orleans, LA **1979 – 1986**
Trial Attorney, Organized Crime and Racketeering Section

- Investigated and prosecuted criminal matters involving racketeering, extortion, obstruction of justice, perjury, narcotics, bank robbery, embezzlement, insurance fraud, gambling, and political corruption

PROFESSIONAL AWARDS

Department of Health & Human Services, Office of Inspector General, Integrity Award, 2006
Gary P. Jordan Award for Outstanding Dedication Exemplifying Finest Level of Public Service, District of Maryland United States Attorney's Office, 2002
United States Attorney General's Award for Sustained Superior Performance, 1990
United States Attorney General's Special Commendation Award for Distinguished Service,1985

SELECTED LECTURES AND PUBLICATIONS

American Bar Association, Health Law Section, Health Litigation Interest Group, HLBytes, *New England Compounding Center Convictions,* January 2019
American Bar Association, Health Law Section, Health Litigation Interest Group, Practice Pointers, *The National Provider Identification System – Why We Should Watch our P's and Q's with the NPI*, June 2018
American Bar Association, Health Law Section, Health Litigation Interest Group, HLBytes, *Ransomware Attacks Against Hospitals on the Rise*, April 2016
American Bar Association, Health Law Section, Health Litigation Interest Group, HLBytes, *Enhanced HIPAA Enforcement Likely in 2016*, December 2015
American Health Lawyers Association; *Understanding the Use of Misdemeanors in Health Care Enforcement*, AHLA Connections Magazine, March 2012
Health Law and Compliance Update 2012, Chapter 2, *Voluntary Disclosures; A Guide for the Health Care Executive*, Wolters, Kluwer, January 2012
Ober|Kaler, Oberview, "*Objection, Privilege": Protecting the Attorney Client Privilege amidst the Shifting Sands of False Claims Act Jurisprudence*, December 18, 2011
Ober|Kaler Health Law Alert, *Seeking Shelter during Uncertain Times: Assessing the Federal Quality Assurance Privilege*, Issue 6, 2011
Ober|Kaler Health Law Alert, *Compliance with the Elder Justice Act's Reporting Requirements: Cautionary Tactics in the Face of Continuing Uncertainty*, June 14, 2011
Medical Lab Observer, *Take Steps to Prevent Spoliation when Using Electronic Records*, June 2011
Medical Lab Observer, *Form an Effective Compliance Program*, January 2011
American Health Lawyers Fraud and Abuse Practice Group Alert, *The Justice Department Turns Up the HEAT on Alleged Medicare Fraud in Detroit*, July 7, 2009
American Health Lawyer Association; *The Foreign Corrupt Practices Act & Health Care; The Case for Global Due Diligence*; Webinar, June 25, 2009
Louisiana State University Medical System; *Conflicts of Interest in the Research Enterprise, Webinar*, February 28, 2009

STATE BAR ADMISSIONS & PROFESSIONAL ASSOCIATIONS

- Virginia, New York, Pennsylvania, Maryland, and Louisiana
- Certified in Healthcare Research Compliance (CHRC)
- American Bar Association, Litigation & Risk Management Interest Group

- American Bar Association, Health Law Section, Co-Chair, Health Law Policy & Coordinating Committee, 2019-2021
- American Health Lawyer's Association, Fraud & Abuse & Life Sciences Section, Vice Chair, Publications, 2020-2021
- Health Care Compliance Association

EDUCATION

NEW YORK UNIVERSITY SCHOOL OF LAW, New York, NY
LL.M., Taxation, 1987

TULANE UNIVERSITY, New Orleans, LA
JD, 1978

- Federal Student Clerkship: Judge Frederick J. R. Heebe, E.D. of LA, 1997 - 1978.

LAFAYETTE COLLEGE, Easton, PA
BA, *cum laude*, Art History, 1975

EXPERT DEPOSITION TESTIMONY

- *U.S. ex rel. Bilotta v. Novartis Pharmaceutical Co*., Case No.1:11-cv-000071, SDNY
  - Deposition, January 22, 2018

- *U.S. ex rel. Penelow v. Janssen Products*, Case No. 12-7758, DNJ
  - Deposition, August 12, 2020